US3112173 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:16:38

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US3112173
Form: Participant Creation
Data signed: (b) (4) **02 Apr 2021 21:10:14**
Generated On: 09 Jun 2021 15:16:38

Participant ID	US3112173

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0504272

US3112173
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504273

US3112173
Folder: Screening
Form: Demographics
Data signed: (b) (4) **19 Feb 2021 16:57:01**
Generated On: 09 Jun 2021 15:16:38

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-0504274

US3112173
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **19 Feb 2021 16:57:01**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504275

US3112173
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **19 Feb 2021 16:57:01**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504276

US3112173
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0504277

US3112173
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	RIGHT EYE/OD CATARACT
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0504278

US3112173
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504279

US3112173
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	RIGHT EYE/OD HERPETIC OPHTHALMIC
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3112173
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504281

US3112173
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504282

US3112173
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	DEPRESSION
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-2022-1614-0504283

US3112173
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	ALLERGY TO DOXYCYCLINE (RASH)
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)	

US3112173
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	ALLERGY TO LEVAQUIN (TENDINITIS)
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-2022-1614-0504285

US3112173
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	OSTEOPOROSIS/DJD
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-2022-1614-0504286

US3112173
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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US3112173
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	LAMINECTOMY (L4-L5)
Start date (dd MMM yyyy)	UN MAR 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN MAR 1987
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1987
Start Year (derived)	1987
Stop Month and Year (derived)	MAR 1987
Stop Year (derived)	1987

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US3112173
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
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Condition	NERVE PAIN AND NEURALGIA-LOWER BACK AND BILATERAL LEGS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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US3112173
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
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Condition	LEFT FOREARM FRACTURE S/P MVA
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

FDA-CBER-2022-1614-0504291

US3112173
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	DEGENERATIVE DISC DISEASE OF LUMBAR SPINE
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)	

US3112173
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	RIGHT OVARIAN MASS
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

FDA-CBER-2022-1614-0504293

US3112173
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	LOWER BACK/SCIATIC PAIN
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN MAR 1987
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	MAR 1987
Stop Year (derived)	1987

FDA-CBER-2022-1614-0504294

US3112173
Folder: Screening
Form: Medical History (18)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504295

US3112173
Folder: Screening
Form: Medical History (19)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	INSOMNIA
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-2022-1614-0504296

US3112173
Folder: Screening
Form: Medical History (20)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504297

US3112173
Folder: Screening
Form: Medical History (21)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	BASAL CELL CARCINOMA
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-2022-1614-0504298

US3112173
Folder: Screening
Form: Medical History (22)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

FDA-CBER-2022-1614-0504299

US3112173
Folder: Screening
Form: Medical History (23)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	OPEN HEART SURGERY - CORONARY STENT
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

FDA-CBER-2022-1614-0504300

US3112173
Folder: Screening
Form: Medical History (24)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Condition	LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

FDA-CBER-2022-1614-0504301

US3112173
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	12:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:20
Height *(xxx.x)*	64 in
Weight *(xxx.x)*	157 lb
BMI *(xxx.x)*	27.00534 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)	

US3112173
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504303

US3112173
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **19 Feb 2021 16:57:01**
Generated On: 09 Jun 2021 15:16:38

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)*	UN UNK 1992
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0504304

US3112173
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

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	(b) (6)
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

FDA-CBER-2022-1614-0504305

US3112173
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 16:57:02**
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504307

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

What was the date of randomization? *(dd MMM yyyy)*	10 AUG 2020
What was the participant's randomization number?	184857
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-2022-1614-0504308

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Height	ND - Not Done
Weight	ND - Not Done

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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)*	12:20 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:20
Temperature *(xxx.x)*	97.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	076 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	084 mmHg
Diastolic Blood Pressure units	MMHG

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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)*	14:02 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:02
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	068 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	082 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0504311

US3112173
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504312

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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)*	14:01 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 14:01
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-2022-1614-0504313

US3112173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	10 AUG 2020
Collection time *(00:00-23:59)*	13:17 (24 HR)
Collection date and time (derived)	10 AUG 2020 13:17

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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	13:12	10 AUG 2020 13:12
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0504315

US3112173
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504316

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	10 AUG 2020 14:36
PC Open Date & Time	10 AUG 2020 14:21
PC Close Date & Time	10 AUG 2020 16:51

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	10 AUG 2020 19:41
PC Open Date & Time	10 AUG 2020 17:46
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0504318

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 AUG 2020 20:41
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0504319

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	12 AUG 2020 18:38
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0504320

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38

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**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	13 AUG 2020 21:14
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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	14 AUG 2020 20:59
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0504322

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	15 AUG 2020 20:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0504323

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 AUG 2020 20:06
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0504324

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 8

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

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

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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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	17 AUG 2020 23:01
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0504325

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 9

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 AUG 2020 21:24
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0504326

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 10

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	19 AUG 2020 21:04
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0504327

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 11

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	20 AUG 2020 21:05
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0504328

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 12

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	21 AUG 2020 21:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0504329

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 13

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	22 AUG 2020 19:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-0504330

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 14

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 AUG 2020 21:18
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0504331

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 15

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	24 AUG 2020 18:27
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-0504332

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 16

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 AUG 2020 17:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0504333

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 17

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
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	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-0504334

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 18

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

FDA-CBER-2022-1614-0504335

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38

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 14:38
PC Open Date & Time	10 AUG 2020 14:21
PC Close Date & Time	10 AUG 2020 16:51

FDA-CBER-2022-1614-0504336

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

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	10 AUG 2020 19:42
PC Open Date & Time	10 AUG 2020 17:46
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0504337

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38

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 20:43
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0504338

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38

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 18:39
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0504339

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38

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 21:15
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38

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 21:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0504341

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38

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 20:32
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38

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 20:06
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0504343

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

FDA-CBER-2022-1614-0504344

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	10 AUG 2020 14:39
PC Open Date & Time	10 AUG 2020 14:21
PC Close Date & Time	10 AUG 2020 16:51

FDA-CBER-2022-1614-0504345

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 ☐

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	10 AUG 2020 19:43
PC Open Date & Time	10 AUG 2020 17:46
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0504347

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504348

	Yes ☐
PC Time stamp	11 AUG 2020 20:43
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504350

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	12 AUG 2020 18:40
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0504351

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504352

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	13 AUG 2020 21:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0504353

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504354

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	14 AUG 2020 21:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0504355

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504356

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	15 AUG 2020 20:32
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0504357

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504358

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	16 AUG 2020 20:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0504359

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 AUG 2020 23:01
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 AUG 2020 21:24
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 21:04
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-0504362

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 21:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-0504363

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 AUG 2020 21:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-0504364

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	22 AUG 2020 19:55
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 AUG 2020 21:19
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-0504366

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 15
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	24 AUG 2020 18:28
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-0504367

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	25 AUG 2020 17:05
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-0504368

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504369

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-0504370

US3112173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 AUG 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments	COULD NOT REACH SUBJECT

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-0504371

US3112173
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504372

US3112173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504373

US3112173
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504374

US3112173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504375

US3112173
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504376

US3112173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-0504377

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 SEP 2020
Time of assessment *(00:00-23:59)*	10:33 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:33
Temperature *(xxx.x)*	98.0 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)*	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	58 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0504378

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 SEP 2020
Time of assessment *(00:00-23:59)*	12:36 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:36
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	59 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0504379

US3112173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	10 SEP 2020

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

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:01 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 12:01
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-2022-1614-0504381

US3112173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	10 SEP 2020
Collection time *(00:00-23:59)*	10:55 (24 HR)
Collection date and time (derived)	10 SEP 2020 10:55

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Collection date *(dd MMM yyyy)*			10 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	10 SEP 2020 10:45
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0504383

US3112173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504384

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38

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**	
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 SEP 2020 12:21
PC Close Date & Time	10 SEP 2020 14:51

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020 15:46
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0504386

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504387

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**	
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	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	14 SEP 2020 10:52
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-0504389

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	14 SEP 2020 16:58
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0504390

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	15 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0504391

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 SEP 2020 12:32
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0504392

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 8

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 SEP 2020 03:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 9

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	18 SEP 2020 14:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0504394

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 10

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	19 SEP 2020 12:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0504395

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 11

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	20 SEP 2020 12:03
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0504396

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 12

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	21 SEP 2020 13:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0504397

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 13

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	22 SEP 2020 16:37
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0504398

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 14

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 SEP 2020 12:14
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0504399

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 15

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	24 SEP 2020 13:53
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0504400

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 16

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 12:43
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0504401

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 17

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	26 SEP 2020 12:14
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0504402

TIMEPOINT	DAY 18

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	27 SEP 2020 12:50
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 19

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	28 SEP 2020 13:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0504404

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 20

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	29 SEP 2020 13:18
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0504405

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 21

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	30 SEP 2020 12:46
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0504406

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 22

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	01 OCT 2020 12:09
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0504407

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 23

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	03 OCT 2020 09:38
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0504408

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 24

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	03 OCT 2020 12:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0504409

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 25

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	04 OCT 2020 12:08
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 26

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	05 OCT 2020 12:04
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0504411

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 27

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	06 OCT 2020 12:10
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-0504412

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 28

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	07 OCT 2020 13:44
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-0504413

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 29

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-0504414

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 30

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 ■
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■
	No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	09 OCT 2020 12:25
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-0504415

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 31

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 ■
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■
	No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	10 OCT 2020 12:17
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

FDA-CBER-2022-1614-0504416

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 ☐
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 SEP 2020 12:21
PC Close Date & Time	10 SEP 2020 14:51

FDA-CBER-2022-1614-0504417

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020 15:46
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0504418

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504420

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38

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	14 SEP 2020 10:53
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020 16:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38

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 SEP 2020 12:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 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 ☐

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US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	10 SEP 2020 12:21
PC Close Date & Time	10 SEP 2020 14:51

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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-2022-1614-0504427

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	10 SEP 2020 15:46
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0504428

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 ☐

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

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

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

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38

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 ■

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US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	14 SEP 2020 10:54
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-0504434

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504435

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	14 SEP 2020 16:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0504436

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38

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 ■

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US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	15 SEP 2020 12:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0504438

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504439

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38

	Yes ☐
PC Time stamp	16 SEP 2020 12:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0504440

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	18 SEP 2020 03:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-0504441

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 14:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0504442

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 SEP 2020 12:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 SEP 2020 12:04
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 SEP 2020 13:00
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0504445

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	22 SEP 2020 16:37
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0504446

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 SEP 2020 12:14
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 15
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	24 SEP 2020 13:54
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0504448

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 SEP 2020 12:43
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0504449

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	26 SEP 2020 12:14
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0504450

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	27 SEP 2020 12:50
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0504451

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	28 SEP 2020 13:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0504452

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 20
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	29 SEP 2020 13:18
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0504453

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	30 SEP 2020 12:46
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 22
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 12:09
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0504455

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 23
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 OCT 2020 09:38
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0504456

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 24
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	03 OCT 2020 12:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 25
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	04 OCT 2020 12:08
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0504458

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 26
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	05 OCT 2020 12:04
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 27
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 OCT 2020 12:11
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-0504460

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 28
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	07 OCT 2020 13:44
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-0504461

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 29
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-0504462

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	09 OCT 2020 12:25
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-0504463

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 31
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	10 OCT 2020 12:17
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

FDA-CBER-2022-1614-0504464

US3112173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504465

US3112173
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:41:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504466

US3112173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 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-2022-1614-0504467

US3112173
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504468

US3112173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504469

US3112173
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504470

US3112173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-0504471

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 OCT 2020
Time of assessment *(00:00-23:59)*	14:22 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 14:22
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0504472

US3112173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504473

US3112173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	08 OCT 2020
Collection time *(00:00-23:59)*	14:35 (24 HR)
Collection date and time (derived)	08 OCT 2020 14:35

FDA-CBER-2022-1614-0504474

US3112173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 20:56:40**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504475

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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	10 OCT 2020 12:17:44
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

FDA-CBER-2022-1614-0504476

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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	19 OCT 2020 11:01:33
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-0504477

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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	24 OCT 2020 11:09:20
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

FDA-CBER-2022-1614-0504478

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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	07 NOV 2020 00:48:17
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

FDA-CBER-2022-1614-0504479

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 11:18:34
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

FDA-CBER-2022-1614-0504480

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 01:05:48
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-0504481

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 10:11:16
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-0504482

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 09:51:02
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-0504483

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 12:40:57
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

FDA-CBER-2022-1614-0504484

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 00:01:48
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-0504485

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 12:04:38
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 00:02:00
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

FDA-CBER-2022-1614-0504487

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 00:21:47
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

FDA-CBER-2022-1614-0504488

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 00:01:53
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

FDA-CBER-2022-1614-0504489

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 10:15:58
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

FDA-CBER-2022-1614-0504490

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 00:02:14
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

FDA-CBER-2022-1614-0504491

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:01:58
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

FDA-CBER-2022-1614-0504492

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 19:07:56
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

FDA-CBER-2022-1614-0504493

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 16:31:34
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

FDA-CBER-2022-1614-0504494

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	24 FEB 2021 08:03:31
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

FDA-CBER-2022-1614-0504495

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 00:03:55
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

FDA-CBER-2022-1614-0504496

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 10:18:21
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

FDA-CBER-2022-1614-0504497

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 09:53:22
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

FDA-CBER-2022-1614-0504498

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 08:12:21
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

FDA-CBER-2022-1614-0504499

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 08:40:55
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 08:44:42
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

FDA-CBER-2022-1614-0504501

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 11:05:17
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	21 APR 2021 13:17:54
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

FDA-CBER-2022-1614-0504503

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 APR 2021 10:58:04
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

FDA-CBER-2022-1614-0504504

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504506

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504516

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504518

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504519

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504520

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

FDA-CBER-2022-1614-0504521

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504522

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
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Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504530

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504534

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

FDA-CBER-2022-1614-0504535

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504538

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504540

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

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504544

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504545

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504546

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504547

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

FDA-CBER-2022-1614-0504548

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504550

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504552

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

FDA-CBER-2022-1614-0504554

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 NOV 2021 00:01
Patient Cloud Close Date & Time	07 NOV 2021 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504559

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

FDA-CBER-2022-1614-0504562

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504564

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504566

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

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

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504571

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504572

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

FDA-CBER-2022-1614-0504574

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504575

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504576

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

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504584

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504586

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504587

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504590

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504592

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504594

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504596

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

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504600

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504602

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504604

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 APR 2022 00:01
Patient Cloud Close Date & Time	24 APR 2022 23:59

FDA-CBER-2022-1614-0504606

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504608

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	29 MAY 2022 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504625

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

FDA-CBER-2022-1614-0504634

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 AUG 2022 00:01
Patient Cloud Close Date & Time	07 AUG 2022 23:59

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504641

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504646

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504650

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504652

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

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38

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

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 00:04:11

US3112173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:48:05**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 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-2022-1614-0504658

US3112173
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:48:05**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504659

US3112173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0504660

US3112173
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504661

US3112173
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0504662

US3112173
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504663

US3112173
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504664

US3112173
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:10:22**
Generated On: 09 Jun 2021 15:16:38

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-0504666

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **02 Apr 2021 21:10:22**
Generated On: 09 Jun 2021 15:16:38

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	9 MAR 2021
Time of assessment *(00:00-23:59)*	11:54 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 11:54
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0504667

US3112173
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:10:22**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504668

US3112173
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:10:22**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	9 MAR 2021
Collection time *(00:00-23:59)*	12:05 (24 HR)
Collection date and time (derived)	9 MAR 2021 12:05

FDA-CBER-2022-1614-0504669

US3112173
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:22**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504670

US3112173
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **08 Apr 2021 22:53:26**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0504671

US3112173
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **08 Apr 2021 22:53:26**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504672

US3112173
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504673

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

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504675

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504677

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	5 JAN 2021
Time of assessment *(00:00-23:59)*	13:37 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 13:37
Temperature *(xxx.x)*	98 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 JAN 2021
Time of assessment *(00:00-23:59)*	14:31 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 14:31
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	5 JAN 2021
What was the treatment time? *(00:00-23:59)*	14:00 (24 HR)
Treatment Date and Time (derived)	5 JAN 2021 14:00
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 JAN 2021
Collection time *(00:00-23:59)*	13:46 (24 HR)
Collection date and time (derived)	5 JAN 2021 13:46

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 JAN 2021
Collection time *(00:00 - 23:59)*	13:42
Collection Date and Time (derived)	5 JAN 2021 13:42

FDA-CBER-2022-1614-0504683

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504684

US3112173
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0504685

US3112173
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-0504686

US3112173
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-0504687

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 FEB 2021
Time of assessment *(00:00-23:59)*	13:09 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:09
Temperature *(xxx.x)*	98 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 FEB 2021
Time of assessment *(00:00-23:59)*	13:55 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 13:55
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3112173
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	2 FEB 2021

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

US3112173
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	2 FEB 2021
What was the treatment time? *(00:00-23:59)*	13:24 (24 HR)
Treatment Date and Time (derived)	2 FEB 2021 13:24
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-2022-1614-0504691

US3112173
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504692

US3112173
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504693

US3112173
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

FDA-CBER-2022-1614-0504694

US3112173
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

FDA-CBER-2022-1614-0504695

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	9 MAR 2021
Time of assessment *(00:00-23:59)*	11:54 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 11:54
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0504696

US3112173
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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-2022-1614-0504697

US3112173
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	9 MAR 2021
Collection time *(00:00-23:59)*	12:05 (24 HR)
Collection date and time (derived)	9 MAR 2021 12:05

US3112173
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **19 Mar 2021 20:23:13**
Generated On: 09 Jun 2021 15:16:38

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0504699

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

AEID	
Adverse event	PAIN SECONDARY TO SPINAL FUSION
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 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	21 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

AEID	
Adverse event	POOR WOUND HEALING
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	17 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)*	03 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

AEID	
Adverse event	DISLOCATED LEFT HIP
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)*	18 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	18 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

AEID	USA-US062-2021-MRNA-1273-P30 1000017
Adverse event	REVISION OF LEFT HIP REPLACEMENT
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)*	19 APR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	19 APR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 APR 2021
Hospital Discharge Date *(dd MMM yyyy)*	20 APR 2021
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **28 Apr 2021 21:49:31**
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

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

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

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	FLECAINIDE
Prophylaxis	Yes ☐ No ■
Indication	ARRHYTHMIA-PVC
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	Q12°
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 MAY 2016
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 ☐

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ■
Indication	NERVE PAIN, NEURALGIA
Dose per administration	900
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0504711

	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 APR 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 ■

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	PRED FORTE
Prophylaxis	Yes ☐ No ■
Indication	OPHTHALMIC HERPES-RIGHT EYE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	DROP, EACH EYE
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 ■

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	FAMCICLOVIR
Prophylaxis	Yes ☐ No ■
Indication	OPHTHALMIC HERPES RIGHT EYE
Dose per administration	500
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

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

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
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 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 ■

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

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

Name of Medication	NORCO
Prophylaxis	Yes ☐ No ■
Indication	BACK AND LEG PAIN
Dose per administration	7.5/325
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 AUG 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	BACK AND LEG PAIN
Dose per administration	800
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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	FISH OIL
Prophylaxis	Yes ☐ No ■
Indication	HEART SUPPLEMENT
Dose per administration	1200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ■ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	QUNOL
Prophylaxis	Yes ☐ No ■
Indication	HEART SUPPLEMENT
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 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 ■

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ■
Indication	BONE HEALTH
Dose per administration	600
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 ■

Name of Medication	FOSAMAX
Prophylaxis	Yes ☐ No ■
Indication	OSTEOPOROSIS
Dose per administration	70
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 ☐

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

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

Name of Medication	VITAMIN D
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	2000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ■ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

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

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

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

Name of Medication	VOLTAREN GEL
Prophylaxis	Yes ☐ No ■
Indication	BACK AND MUSCLE PAIN
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)*	UN JUN 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)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

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

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	UN DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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

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

Name of Medication	SEPTRA DS
Prophylaxis	Yes ☐ No ■
Indication	POOR WOUND HEALING
Dose per administration	160/800
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	17 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	27 SEP 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 ■

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	KEFLEX
Prophylaxis	Yes ☐ No ■
Indication	POOR WOUND HEALING
Dose per administration	500
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ■ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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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)*	17 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)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-0504752

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Name of Medication	ROBAXIN
Prophylaxis	Yes ☐ No ■
Indication	PAIN SECONDARY TO SPINAL FUSION
Dose per administration	750
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)*	24 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 SEP 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 ■

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 APR 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 APR 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 APR 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	REVISION OF LEFT HIP REPLACEMENT
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 APR 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **02 Apr 2021 21:10:15**
Generated On: 09 Jun 2021 15:16:38

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0504761

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **23 Apr 2021 21:02:37**
Generated On: 09 Jun 2021 15:16:38

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
24 AUG 2020	SPINAL FUSION	Medical History	
18 FEB 2021	LEFT HIP RELOCATION	Adverse Event	
19 APR 2021	REVISION OF LEFT HIP REPLACEMENT	Adverse Event	

FDA-CBER-2022-1614-0504762

US3112173
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 15:16:38

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

FDA-CBER-2022-1614-0504763

US3112173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:16:38

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

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Data signed: (b) (4) **28 Apr 2021 21:49:39**
Generated On: 09 Jun 2021 15:16:38

SAEID	USA-US062-2021-MRNA-1273-P301000017
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form (1)
Data signed: (b) (4) **28 Apr 2021 21:49:39**
Generated On: 09 Jun 2021 15:16:38

SAEID	USA-US062-2021-MRNA-1273-P301000017
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	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	26/APR/2021 14:22
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

FDA-CBER-2022-1614-0504766

Audit

US3112173 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112173
Form: Participant Creation
Generated On: 09 Jun 2021 15:16:38
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:26
User entered 'US3112173'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 20:19:08

FDA-CBER-2022-1614-0504768

US3112173
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:20

FDA-CBER-2022-1614-0504769

US3112173
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:33
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 20:19:09

US3112173
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:33
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:20

US3112173
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'SCRN'	System	10 Aug 2020 21:08:20

FDA-CBER-2022-1614-0504772

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 20:19:10

FDA-CBER-2022-1614-0504773

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '77'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504774

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'YEARS'	System	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504775

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '77'	System	10 Aug 2020 21:08:30

FDA-CBER-2022-1614-0504776

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered 'Female (F)'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504779

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504781

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504784

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:08:46

FDA-CBER-2022-1614-0504785

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:16:38
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:57:42
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:08:46

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered '10 Aug 2020'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

FDA-CBER-2022-1614-0504788

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Aug 2020'	System	10 Aug 2020 21:08:30

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2020'	System	10 Aug 2020 21:08:30

FDA-CBER-2022-1614-0504790

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

FDA-CBER-2022-1614-0504792

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

FDA-CBER-2022-1614-0504793

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered 'No (N)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:30

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:00
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 20:19:09

US3112173
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:16:38
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1'	System	10 Aug 2020 21:08:34

FDA-CBER-2022-1614-0504797

US3112173
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 15:16:38
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:58:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:34

FDA-CBER-2022-1614-0504798

US3112173
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 15:16:38
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
Query 'Source listed down open heart surgery in 2016. Please verify indication and add to EDC' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:18:21
User opened query 'Source listed down open heart surgery in 2016. Please verify indication and add to EDC' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 23:38:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:01:28
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 02:42:48
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'MED HX UPDATED' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 14:21:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:21:39
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:02:48
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:05:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:05:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:05:43
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:05:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:05:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:36:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:12:33

FDA-CBER-2022-1614-0504799

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:05:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 09:05:18
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:14:48
User entered 'Right Eye/OD Cataract'	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2015'	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2015'	System	14 Aug 2020 14:13:53

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2015'	System	14 Aug 2020 14:13:53

FDA-CBER-2022-1614-0504807

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:13:53

FDA-CBER-2022-1614-0504808

US3112173
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:13:53

FDA-CBER-2022-1614-0504809

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:44:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:44:46
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:14:48
User entered 'Left Eye/OD Cataract'	(b) (4), (b) (6)	14 Aug 2020 14:14:25

FDA-CBER-2022-1614-0504810

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2017'	System	14 Aug 2020 14:14:25

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2017'	System	14 Aug 2020 14:14:25

FDA-CBER-2022-1614-0504817

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:14:25

FDA-CBER-2022-1614-0504818

US3112173
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:14:25

FDA-CBER-2022-1614-0504819

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes ophthalmic, LLT: Herpes ophthalmic - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 07:57:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 07:57:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:02
User closed query 'Source lists this down as ophthalmic herpes. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:32:57
Data point term sent to Coder	System	19 Nov 2020 19:00:50
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 19:00:32
Coding entries removed.	Matthew Musikanth (b) (4)	19 Nov 2020 19:00:32
User entered 'RIGHT EYE/OD HERPETIC ophthalmic' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 19:00:32
Query 'Source lists this down as ophthalmic herpes. Please verify and update. ' answered with 'as documented in med history' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:50:09
User opened query 'Source lists this down as ophthalmic herpes. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 23:00:56
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes ophthalmic, LLT: Herpes ophthalmic - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 13:45:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 13:45:32
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:18:01
User entered 'RIGHT EYE/OD Herpetic' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:17:08
Data point term sent to Coder	System	14 Aug 2020 14:16:55
User entered 'Right Eye/OD'	(b) (4), (b) (6)	14 Aug 2020 14:15:55

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 14:17:08
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:17:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 14:15:55
User entered ' 2017' (non-conformant).	(b) (4), (b) (6)	14 Aug 2020 14:15:55

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504823

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	15 Oct 2020 22:05:55
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	15 Oct 2020 22:05:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:05:20
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:15:55

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:15:55

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	15 Oct 2020 22:05:55
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504826

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2017'	System	14 Aug 2020 14:17:08
User entered empty.	System	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504827

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2017'	System	14 Aug 2020 14:17:08
User entered empty.	System	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504828

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504829

US3112173
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:15:55

FDA-CBER-2022-1614-0504830

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
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)	14 Aug 2020 14:19:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:19:17
Data point term sent to Coder	System	14 Aug 2020 14:18:01
User entered 'Hypertension'	(b) (4), (b) (6)	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504831

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504832

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504833

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:17:31

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504835

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:17:31

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2019'	System	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504837

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2019'	System	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504838

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504839

US3112173
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:17:31

FDA-CBER-2022-1614-0504840

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
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)	14 Aug 2020 14:19:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:19:17
Data point term sent to Coder	System	14 Aug 2020 14:18:04
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	14 Aug 2020 14:18:03

FDA-CBER-2022-1614-0504841

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:18:03

FDA-CBER-2022-1614-0504845

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2018'	System	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2018'	System	14 Aug 2020 14:18:03

FDA-CBER-2022-1614-0504848

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:18:03

US3112173
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:18:03

FDA-CBER-2022-1614-0504850

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
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)	14 Aug 2020 14:19:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:19:18
Data point term sent to Coder	System	14 Aug 2020 14:19:04
User entered 'Depression'	(b) (4), (b) (6)	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504851

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2010'	(b) (4), (b) (6)	14 Aug 2020 14:18:22

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:18:22

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:18:22

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:18:22

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504856

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2010'	System	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504857

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2010'	System	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504858

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504859

US3112173
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:18:22

FDA-CBER-2022-1614-0504860

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 11:54:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 11:54:51
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)	18 Nov 2020 08:13:10
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 08:13:10
User closed query 'Source lists this as allergy to doxycycline. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 01:57:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 01:57:08
Data point term sent to Coder	System	18 Nov 2020 00:00:49
Query 'Source lists this as allergy to doxycycline. Please verify and update. ' answered with 'updated' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 23:59:57
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 23:59:52
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 23:59:52
User entered 'allergy to DOXYCYCLINE (RASH)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 23:59:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User opened query 'Source lists this as allergy to doxycycline. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:03:44
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:52
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:21:06
User entered 'Doxycycline (Rash)'	(b) (4), (b) (6)	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 1999'	(b) (4), (b) (6)	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:20:09

FDA-CBER-2022-1614-0504865

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1999'	System	14 Aug 2020 14:20:09

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1999'	System	14 Aug 2020 14:20:09

FDA-CBER-2022-1614-0504869

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:20:09

FDA-CBER-2022-1614-0504870

US3112173
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:20:09

FDA-CBER-2022-1614-0504871

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
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: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:36:02
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 18:36:02
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)	18 Nov 2020 08:13:09
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 08:13:09
User closed query 'Source lists this as allergy to levaquin. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 01:57:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 01:57:21
Data point term sent to Coder	System	18 Nov 2020 00:09:52
Query 'Source lists this as allergy to levaquin. Please verify and update. ' answered with 'updated' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 00:09:20
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 00:09:15
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 00:09:15
User entered 'allergy to LEVAQUIN (TENDINITIS)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	18 Nov 2020 00:09:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User opened query 'Source lists this as allergy to levaquin. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:04:32

FDA-CBER-2022-1614-0504872

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 08:28:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 08:28:36
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:22:07
User entered 'Levaquin (tendinitis)'	(b) (4), (b) (6)	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504873

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2005'	(b) (4), (b) (6)	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504874

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504875

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:21:09

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504877

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:21:09

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2005'	System	14 Aug 2020 14:21:09

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2005'	System	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504880

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504881

US3112173
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:21:09

FDA-CBER-2022-1614-0504882

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:22:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 13:22:51
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:23:11
User entered 'Osteoporosis/DJD'	(b) (4), (b) (6)	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504883

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2019'	(b) (4), (b) (6)	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504884

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504885

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504886

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:22:25

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:22:25

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2019'	System	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504889

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2019'	System	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504890

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504891

US3112173
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:22:25

FDA-CBER-2022-1614-0504892

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Ankle, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:48:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:50:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:50:33
Data point term sent to Coder	System	15 Oct 2020 21:49:55
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Ankle, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:49:38
Coding entries removed.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:49:30
User entered 'OSTEOARTHRITIS-generalized' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:49:30
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Ankle, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:55:03
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
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 14:24:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:24:24
Data point term sent to Coder	System	14 Aug 2020 14:23:11
User entered 'Osteoarthritis'	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2018'	System	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2018'	System	14 Aug 2020 14:22:54

FDA-CBER-2022-1614-0504901

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:22:54

US3112173
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	14 Aug 2020 14:22:54

FDA-CBER-2022-1614-0504903

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 13:38:07
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	20 Oct 2020 23:54:58
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:55:12
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:25:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 14:25:20
Data point term sent to Coder	System	14 Aug 2020 14:24:12
User entered 'Hysterectomy'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 1992' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Oct 2020 23:54:54
User entered 'UN UNK 1988'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

FDA-CBER-2022-1614-0504907

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Oct 2020 23:55:06
User entered 'UN UNK 1992' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:06
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	20 Oct 2020 23:54:54
User entered 'UN UNK 1988'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1992'	System	20 Oct 2020 23:54:54
User entered 'Jan 1988'	System	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1992'	System	20 Oct 2020 23:54:54
User entered '1988'	System	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1992'	System	20 Oct 2020 23:55:06
User entered 'Jan 1988'	System	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1992'	System	20 Oct 2020 23:55:06
User entered '1988'	System	14 Aug 2020 14:23:39

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 13:39:24
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:47
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 05:55:22
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Lumbar laminectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 10:54:16

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 10:54:16
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:25:15
User entered 'Laminectomy (L4-L5)'	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'un Mar 1987' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:40
User entered 'UN UNK 1976'	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:25:17
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 14:24:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN Mar 1987' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:40
User entered 'UN UNK 1976' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:25:17
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Mar 1987'	System	20 Oct 2020 23:56:40
User entered 'Jan 1976'	System	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1987'	System	20 Oct 2020 23:56:40
User entered '1976'	System	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Mar 1987'	System	20 Oct 2020 23:56:40
User entered 'Jan 1976'	System	14 Aug 2020 14:25:17
User entered empty.	System	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1987'	System	20 Oct 2020 23:56:40
User entered '1976'	System	14 Aug 2020 14:25:17
User entered empty.	System	14 Aug 2020 14:24:58

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Neuralgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:42:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:42:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
Data point term sent to Coder	System	15 Oct 2020 22:03:23
User entered 'nerve pain and neuralgia-lower back and bilateral legs'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2017'	Karen Mylerberg (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	Karen Mylerberg (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2017'	System	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2017'	System	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	15 Oct 2020 22:03:23
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:24

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	05 Sep 2020 14:21:39
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Forearm fracture, LLT: Forearm fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:51:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:51:35
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:43
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	20 Aug 2020 20:05:39
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	14 Aug 2020 14:36:14
Data point term sent to Coder	System	14 Aug 2020 14:27:18
User entered 'Left Forearm Fracture S/P MVA'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504936

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2001'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504937

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2001'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504940

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504941

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2001'	System	14 Aug 2020 14:26:52

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2001'	System	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504943

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2001'	System	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504944

US3112173
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2001'	System	14 Aug 2020 14:26:52

FDA-CBER-2022-1614-0504945

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 01:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 01:19:38
Data point term sent to Coder	System	16 Oct 2020 17:23:24
User entered 'Degenerative disc disease of lumbar spine'	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2019'	Karen Mylerberg (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	Karen Mylerberg (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2019'	System	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

FDA-CBER-2022-1614-0504952

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2019'	System	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

FDA-CBER-2022-1614-0504953

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

FDA-CBER-2022-1614-0504954

US3112173
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	16 Oct 2020 17:22:29
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:21:49
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	20 Aug 2020 21:39:29

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube disorders NEC, PT: Ovarian mass, LLT: Ovarian mass - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 04:49:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 04:49:35
Data point term sent to Coder	System	20 Oct 2020 23:55:36
User entered 'Right Ovarian MAss'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'un UNK 1992'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

FDA-CBER-2022-1614-0504957

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

FDA-CBER-2022-1614-0504958

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'un UNK 1992'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:32

FDA-CBER-2022-1614-0504961

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1992'	System	20 Oct 2020 23:55:32

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1992'	System	20 Oct 2020 23:55:32

FDA-CBER-2022-1614-0504963

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1992'	System	20 Oct 2020 23:55:32

US3112173
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1992'	System	20 Oct 2020 23:55:32

FDA-CBER-2022-1614-0504965

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:22:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:22:09
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
Data point term sent to Coder	System	20 Oct 2020 23:56:36
User entered 'Lower Back/Sciatic Pain'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'un UNK 1987'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504968

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'No (N)'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504969

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'un Mar 1987'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504970

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Matthew Musikanth (b) (4)	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504971

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 1987'	System	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504972

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1987'	System	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504973

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Mar 1987'	System	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504974

US3112173
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '1987'	System	20 Oct 2020 23:56:11

FDA-CBER-2022-1614-0504975

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 03:09:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 03:09:26
Data point term sent to Coder	System	23 Oct 2020 19:02:15
User entered 'Arrythmia-PVC'	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'UN UNK 2015'	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered empty.	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	(b) (4) Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:12:13
User entered '0'	Karen Mylerberg (b) (4)	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2015'	System	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2015'	System	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	23 Oct 2020 19:01:45
DataPoint activated with code reason code Data required.	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:00:32
DataPoint inactivated with code reason code Data not required.	Matthew Musikanth (b) (4)	20 Oct 2020 23:55:48

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
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)	19 Nov 2020 01:04:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 01:04:53
Data point term sent to Coder	System	19 Nov 2020 01:04:04
User entered 'Insomnia'	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504986

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504988

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504990

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:30
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 01:03:41

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2010'	System	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504992

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2010'	System	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504993

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504994

US3112173
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 01:03:41

FDA-CBER-2022-1614-0504995

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
User closed query 'Per MM, please clarify condition and update event term to reflect etiology if possible and rule out bleeding disorder (EC#8)' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 04:16:42
Query 'Per MM, please clarify condition and update event term to reflect etiology if possible and rule out bleeding disorder (EC#8)' answered with 'subject was contacted reason for easy bruisability is unknown ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 19:24:20
User opened query 'Per MM, please clarify condition and update event term to reflect etiology if possible and rule out bleeding disorder (EC#8)' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 18:24:05
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Bleeding tendencies, PT: Increased tendency to bruise, LLT: Increased tendency to bruise - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:16:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:16:02
Data point term sent to Coder	System	19 Nov 2020 19:15:16
User entered 'EAsy Bruisability'	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

FDA-CBER-2022-1614-0504996

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User entered 'un UNK 2017'	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:36:04
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2017'	System	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2017'	System	19 Nov 2020 19:14:47

FDA-CBER-2022-1614-0505003

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 19:14:47

US3112173
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 19:14:47

FDA-CBER-2022-1614-0505005

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:35:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:35:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
Data point term sent to Coder	System	19 Nov 2020 19:19:24
User entered 'Basal Cell Carcinoma'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

FDA-CBER-2022-1614-0505007

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:33:38
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2010'	System	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2010'	System	19 Nov 2020 19:19:19

FDA-CBER-2022-1614-0505013

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 19:19:19

US3112173
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered empty.	System	19 Nov 2020 19:19:19

FDA-CBER-2022-1614-0505015

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:21:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:21:08
Data point term sent to Coder	System	19 Nov 2020 19:20:25
User entered 'Coronary Artery Disease'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:34:14
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2016'	System	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2016'	System	19 Nov 2020 19:19:39

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US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2016'	System	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2016'	System	19 Nov 2020 19:19:39

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:35:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:35:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
Data point term sent to Coder	System	19 Nov 2020 19:20:27
User entered 'Open Heart surgery - Coronary stent'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:40
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2016'	System	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2016'	System	19 Nov 2020 19:20:08

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US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Jan 2016'	System	19 Nov 2020 19:20:08

US3112173
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2016'	System	19 Nov 2020 19:20:08

FDA-CBER-2022-1614-0505035

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:33:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:33:51
Data point term sent to Coder	System	23 Apr 2021 16:33:13
User entered 'Left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'UN Feb 2019'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'UN Feb 2019'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:35:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:32:47

FDA-CBER-2022-1614-0505041

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Feb 2019'	System	23 Apr 2021 16:32:47

FDA-CBER-2022-1614-0505042

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2019'	System	23 Apr 2021 16:32:47

FDA-CBER-2022-1614-0505043

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'Feb 2019'	System	23 Apr 2021 16:32:47

FDA-CBER-2022-1614-0505044

US3112173
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 15:16:38
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '2019'	System	23 Apr 2021 16:32:47

FDA-CBER-2022-1614-0505045

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered '12:20'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered '10 Aug 2020 12:20'	System	14 Aug 2020 14:39:29

FDA-CBER-2022-1614-0505049

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered '64' in	(b) (4), (b) (6)	14 Aug 2020 14:39:29
DataPoint set to visible.	System	10 Aug 2020 21:08:34

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered '157' lb	(b) (4), (b) (6)	14 Aug 2020 14:39:29
DataPoint set to visible.	System	10 Aug 2020 21:08:34

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
Amendment Manager: User entered '27.00534'	System	16 Sep 2020 23:50:42
User entered '27.0'	System	14 Aug 2020 14:39:29
DataPoint set to visible.	System	10 Aug 2020 21:08:34

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'kg/m2'	System	14 Aug 2020 14:39:29
DataPoint set to visible.	System	10 Aug 2020 21:08:34

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 17:11:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:03
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 14:42:16
User entered '97.4' F	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:23:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:03
User entered '076'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'bpm'	System	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:03
User entered '018'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'breaths/min'	System	14 Aug 2020 14:39:29

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US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:03
User entered '130'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'mmHg'	System	14 Aug 2020 14:39:29

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US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:13:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:23:03
User entered '084'	(b) (4), (b) (6)	14 Aug 2020 14:39:29

US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User entered 'mmHg'	System	14 Aug 2020 14:39:29

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US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53

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US3112173
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53

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US3112173
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:14:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:40:07

US3112173
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:14:02
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	23 Sep 2020 23:25:49
User entered '10 Aug 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 23:25:49
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	23 Sep 2020 23:25:43
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	23 Sep 2020 23:25:43
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 23:25:43
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:14:47
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:40:07

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

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US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User closed query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:35:06
Query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:57:55
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:57:15
User opened query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:53:23
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	31 Aug 2020 21:42:59
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	31 Aug 2020 21:42:50
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	31 Aug 2020 21:42:50

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
If No, what is the reason?

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 21:42:50
User closed query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	14 Aug 2020 14:50:29
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	14 Aug 2020 14:49:24
User opened query 'Partner medically sterile or Other has not been entered, however specify is provided. Please correct.' (Site from System).	System	14 Aug 2020 14:49:24
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 14:50:29
User entered 'Hysterectomy'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:17:42
User closed query 'Source listed down 1992 as date of hysterectomy. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:17:36
Query 'Source listed down 1992 as date of hysterectomy. Please verify and update. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:51:45
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:51:35
User entered 'UN UNK 1992' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:51:35
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:15:36
User opened query 'Source listed down 1992 as date of hysterectomy. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:15:32
User entered 'UN UNK 1988' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:57:15
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 21:42:59
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:57:15
User entered 'UN UNK 1988'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:16:38
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:15:36
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:49:24

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

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US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered (b) (6)	(b) (4), (b) (6)	14 Aug 2020 14:44:53

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US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered '1'	(b) (4), (b) (6)	14 Aug 2020 14:44:53

FDA-CBER-2022-1614-0505096

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
User entered '0'	(b) (4), (b) (6) (b) (4)	14 Aug 2020 14:44:53

US3112173
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:16:38
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:48:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:57:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:17:16
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:44:53

US3112173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:53:21

US3112173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:48
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:53:21

US3112173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:17:48
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 14:53:21

FDA-CBER-2022-1614-0505101

US3112173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'VISIT1'	System	14 Aug 2020 14:53:21

FDA-CBER-2022-1614-0505102

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 20:19:14

FDA-CBER-2022-1614-0505103

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:25:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:25:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 20:19:14
User entered '184857' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:19:14

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:19:14

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38

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)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:53:42

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38

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)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:53:42

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:53:42

FDA-CBER-2022-1614-0505108

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:53:42

FDA-CBER-2022-1614-0505109

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:53:42

US3112173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:16:38
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:01
User entered 'No (N)'	Nicolle Mendez (b) (4)	29 Sep 2020 17:01:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:16:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:21:14

FDA-CBER-2022-1614-0505111

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505118

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '12:20'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Aug 2020 12:20'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505120

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '97.4' F	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505122

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '076'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505125

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '018'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '130'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505128

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505129

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '084'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505131

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:21:18
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:23:45
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	14 Aug 2020 14:55:47
User entered '14:02'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Aug 2020 14:02'	System	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '97.2' F	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505140

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505141

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '068'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505143

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '014'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	14 Aug 2020 14:55:47

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '132'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505146

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505147

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:18
User entered '082'	(b) (4), (b) (6)	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505148

US3112173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Aug 2020 14:55:47

FDA-CBER-2022-1614-0505149

US3112173
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:48
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:40:37

US3112173
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:18:48
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:40:37

FDA-CBER-2022-1614-0505151

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
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)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered empty.	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered '10 Aug 2020'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered '14:01'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505157

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Aug 2020 14:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:10
User entered 'ONCE'	System	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 21:08:50

US3112173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:46:58

US3112173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:30
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:46:58

US3112173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:21:30
User entered '13:17'	(b) (4), (b) (6)	14 Aug 2020 14:46:58

US3112173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Aug 2020 13:17'	System	14 Aug 2020 14:46:58

FDA-CBER-2022-1614-0505165

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:38
User entered '10 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:38
User entered '13:12'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

FDA-CBER-2022-1614-0505169

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Aug 2020 13:12'	System	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:38
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:46:28

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:38
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:46:28

FDA-CBER-2022-1614-0505173

US3112173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered empty.	System	14 Aug 2020 14:46:28

FDA-CBER-2022-1614-0505174

US3112173
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:45:42

US3112173
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	14 Aug 2020 14:45:42

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:35:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered 'Yes (Y)'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505178

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:35:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered '97.2'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505179

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:35:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered 'Yes (Y)'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505180

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:07:25
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:30:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Aug 2020 21:36:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:36:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered '1'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505181

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:36:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered '0'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505182

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:36:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f1e3c00e-b825-4309-9bfb-7abe969e4ca0'	System	10 Aug 2020 21:36:12
User entered '10 Aug 2020 14:36'	System	10 Aug 2020 21:36:12

FDA-CBER-2022-1614-0505183

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 14:21'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505184

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 16:51'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505185

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:40:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered 'Yes (Y)'	System	11 Aug 2020 02:41:43

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered '97.1'	System	11 Aug 2020 02:41:43

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered 'Yes (Y)'	System	11 Aug 2020 02:41:43

FDA-CBER-2022-1614-0505189

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:07:30
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:30:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Aug 2020 02:41:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered '1'	System	11 Aug 2020 02:41:43

FDA-CBER-2022-1614-0505190

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered '0'	System	11 Aug 2020 02:41:43

FDA-CBER-2022-1614-0505191

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d17e24a-dfab-448e-8b9d-76ea17c4d748'	System	11 Aug 2020 02:41:43
User entered '10 Aug 2020 19:41'	System	11 Aug 2020 02:41:43

FDA-CBER-2022-1614-0505192

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 17:46'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505193

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505194

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 2'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered 'Yes (Y)'	System	12 Aug 2020 03:41:40

FDA-CBER-2022-1614-0505196

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered '98.0'	System	12 Aug 2020 03:41:40

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered 'Yes (Y)'	System	12 Aug 2020 03:41:40

FDA-CBER-2022-1614-0505198

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:07:36
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:30:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 03:41:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered '1'	System	12 Aug 2020 03:41:40

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered '0'	System	12 Aug 2020 03:41:40

FDA-CBER-2022-1614-0505200

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:41:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e1a2a70d-4fc7-4369-8d1b-bda5c5866cf5'	System	12 Aug 2020 03:41:40
User entered '11 Aug 2020 20:41'	System	12 Aug 2020 03:41:40

FDA-CBER-2022-1614-0505201

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505203

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 3'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered 'Yes (Y)'	System	13 Aug 2020 01:38:56

FDA-CBER-2022-1614-0505205

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered '98.6'	System	13 Aug 2020 01:38:56

FDA-CBER-2022-1614-0505206

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered 'Yes (Y)'	System	13 Aug 2020 01:38:56

FDA-CBER-2022-1614-0505207

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:07:41
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Aug 2020 01:38:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered '1'	System	13 Aug 2020 01:38:56

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered '0'	System	13 Aug 2020 01:38:56

FDA-CBER-2022-1614-0505209

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:38:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a3bc6c5-3524-4653-9d50-982d5c9f283f'	System	13 Aug 2020 01:38:56
User entered '12 Aug 2020 18:38'	System	13 Aug 2020 01:38:56

FDA-CBER-2022-1614-0505210

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505211

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 4'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered 'Yes (Y)'	System	14 Aug 2020 04:14:57

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered '98.1'	System	14 Aug 2020 04:14:57

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered 'Yes (Y)'	System	14 Aug 2020 04:14:57

FDA-CBER-2022-1614-0505216

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:07:46
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 04:14:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered '1'	System	14 Aug 2020 04:14:57

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered '0'	System	14 Aug 2020 04:14:57

FDA-CBER-2022-1614-0505218

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:14:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'dd6ace49-4eba-4325-ac83-61fb1b03eebe'	System	14 Aug 2020 04:14:57
User entered '13 Aug 2020 21:14'	System	14 Aug 2020 04:14:57

FDA-CBER-2022-1614-0505219

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505220

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505221

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 5'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered 'Yes (Y)'	System	15 Aug 2020 03:59:49

FDA-CBER-2022-1614-0505223

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered '98.6'	System	15 Aug 2020 03:59:49

FDA-CBER-2022-1614-0505224

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered 'Yes (Y)'	System	15 Aug 2020 03:59:49

FDA-CBER-2022-1614-0505225

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:08:34
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Aug 2020 03:59:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered '1'	System	15 Aug 2020 03:59:49

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered '0'	System	15 Aug 2020 03:59:49

FDA-CBER-2022-1614-0505227

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b00fe80d-9d30-41a8-971f-1b7d0edc4540'	System	15 Aug 2020 03:59:49
User entered '14 Aug 2020 20:59'	System	15 Aug 2020 03:59:49

FDA-CBER-2022-1614-0505228

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505229

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505230

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 6'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered 'Yes (Y)'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505232

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered '98.3'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505233

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered 'Yes (Y)'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505234

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:08:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Aug 2020 03:31:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered '1'	System	16 Aug 2020 03:31:44

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered '0'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505236

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '854b34f9-c708-4584-9b32-1ae3a29c4d43'	System	16 Aug 2020 03:31:44
User entered '15 Aug 2020 20:31'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505237

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505238

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505239

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 7'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:05:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered 'Yes (Y)'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505241

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered '98.4'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505242

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered 'Yes (Y)'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505243

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:08:45
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	17 Aug 2020 03:06:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered '1'	System	17 Aug 2020 03:06:15

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered '0'	System	17 Aug 2020 03:06:15

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5212a4-dd12-4b39-9701-8f7df5df798e'	System	17 Aug 2020 03:06:15
User entered '16 Aug 2020 20:06'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505246

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505247

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505248

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	16 Aug 2020 03:31:44
User entered 'Day 8'	System	16 Aug 2020 03:31:44

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:00:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered 'Yes (Y)'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505250

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:00:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered '97.9'	System	18 Aug 2020 06:01:08

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:00:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered 'Yes (Y)'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505252

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:08:50
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Aug 2020 06:01:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:00:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered '1'	System	18 Aug 2020 06:01:08

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:00:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered '0'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505254

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:01:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '16d03889-c8e1-4dd1-8571-71736f3a28b2'	System	18 Aug 2020 06:01:08
User entered '17 Aug 2020 23:01'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505255

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505256

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505257

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	17 Aug 2020 03:06:15
User entered 'Day 9'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505258

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered 'Yes (Y)'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505259

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:28', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered '98.3'	System	19 Aug 2020 04:24:46

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered 'Yes (Y)'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505261

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:08:55
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Aug 2020 04:24:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered '1'	System	19 Aug 2020 04:24:46

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered '0'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505263

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a677127c-e9eb-43e3-82e4-9215250ca805'	System	19 Aug 2020 04:24:46
User entered '18 Aug 2020 21:24'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505264

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505265

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505266

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Aug 2020 06:01:08
User entered 'Day 10'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505267

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:03:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered 'Yes (Y)'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505268

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:03:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered '98.1'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505269

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered 'Yes (Y)'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505270

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:01
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	20 Aug 2020 04:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered '1'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505271

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered '0'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505272

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e704abe2-9932-4581-9ab1-ca1d4a53d5d7'	System	20 Aug 2020 04:04:15
User entered '19 Aug 2020 21:04'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505273

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505274

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505275

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	19 Aug 2020 04:24:46
User entered 'Day 11'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505276

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered 'Yes (Y)'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505277

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered '98.1'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505278

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered 'Yes (Y)'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505279

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:09
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:31:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Aug 2020 04:05:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered '1'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505280

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered '0'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505281

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:05:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ccb0c5d7-7410-49ba-986f-21369282a1a0'	System	21 Aug 2020 04:05:58
User entered '20 Aug 2020 21:05'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505282

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505283

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505284

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	20 Aug 2020 04:04:15
User entered 'Day 12'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505285

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered 'Yes (Y)'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505286

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered '97.7'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505287

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered 'Yes (Y)'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505288

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:14
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:32:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Aug 2020 04:29:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered '1'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505289

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered '0'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505290

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8eb25849-6a35-4f5d-b37b-72e2ed15ec18'	System	22 Aug 2020 04:29:39
User entered '21 Aug 2020 21:29'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505291

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505292

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505293

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	21 Aug 2020 04:05:58
User entered 'Day 13'	System	21 Aug 2020 04:05:58

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:54:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered 'Yes (Y)'	System	23 Aug 2020 02:55:08

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:54:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered '97.6'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505296

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:54:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered 'Yes (Y)'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505297

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:19
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:32:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Aug 2020 02:55:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:54:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered '1'	System	23 Aug 2020 02:55:08

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:54:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered '0'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505299

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:55:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5cd5ee6a-2280-4a06-981b-bd0218594ba5'	System	23 Aug 2020 02:55:08
User entered '22 Aug 2020 19:55'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505300

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505301

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505302

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	22 Aug 2020 04:29:39
User entered 'Day 14'	System	22 Aug 2020 04:29:39

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered 'Yes (Y)'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505304

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered '97.7'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505305

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered 'Yes (Y)'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505306

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:24
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:32:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Aug 2020 04:18:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered '1'	System	24 Aug 2020 04:18:57

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered '0'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505308

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '7c96a32a-8d91-49a8-8ca8-3367a45a9e56'	System	24 Aug 2020 04:18:57
User entered '23 Aug 2020 21:18'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505309

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505310

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505311

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	23 Aug 2020 02:55:08
User entered 'Day 15'	System	23 Aug 2020 02:55:08

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:11', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered 'Yes (Y)'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505313

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered '98.3'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505314

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered 'Yes (Y)'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505315

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:29
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:32:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Aug 2020 01:27:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered '1'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505316

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered '0'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505317

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:27:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df8d5197-53b5-4ea8-8d54-60dc22becf8a'	System	25 Aug 2020 01:27:41
User entered '24 Aug 2020 18:27'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505318

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505319

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505320

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	24 Aug 2020 04:18:57
User entered 'Day 16'	System	24 Aug 2020 04:18:57

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered 'Yes (Y)'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505322

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered '98.3'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505323

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered 'Yes (Y)'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505324

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:09:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:32:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Aug 2020 00:04:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered '1'	System	26 Aug 2020 00:04:46

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered '0'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505326

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:04:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3a8714e3-9003-4cb2-b4d0-244aaaefd8cb'	System	26 Aug 2020 00:04:46
User entered '25 Aug 2020 17:04'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505327

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505328

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505329

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	25 Aug 2020 01:27:41
User entered 'Day 17'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505330

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505331

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505332

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505334

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505335

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505336

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505337

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505338

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	26 Aug 2020 00:04:46
User entered 'Day 18'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505339

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505340

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505341

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505342

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505343

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505344

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505345

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505346

US3112173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505347

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:37:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd22f552f-2d5f-4612-aef4-3bc56178356e'	System	10 Aug 2020 21:38:39
User entered 'None (1)'	System	10 Aug 2020 21:38:39

FDA-CBER-2022-1614-0505349

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:37:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd22f552f-2d5f-4612-aef4-3bc56178356e'	System	10 Aug 2020 21:38:39
User entered 'No (N)'	System	10 Aug 2020 21:38:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:38:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd22f552f-2d5f-4612-aef4-3bc56178356e'	System	10 Aug 2020 21:38:39
User entered 'No (N)'	System	10 Aug 2020 21:38:39

FDA-CBER-2022-1614-0505351

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:38:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd22f552f-2d5f-4612-aef4-3bc56178356e'	System	10 Aug 2020 21:38:39
User entered 'None (1)'	System	10 Aug 2020 21:38:39

FDA-CBER-2022-1614-0505352

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:38:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd22f552f-2d5f-4612-aef4-3bc56178356e'	System	10 Aug 2020 21:38:39
User entered '10 Aug 2020 14:38'	System	10 Aug 2020 21:38:39

FDA-CBER-2022-1614-0505353

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 14:21'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505354

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 16:51'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505355

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:41:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ecb5f840-b6b4-436f-ae28-66651072b30b'	System	11 Aug 2020 02:42:48
User entered 'None (1)'	System	11 Aug 2020 02:42:48

FDA-CBER-2022-1614-0505357

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:42:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ecb5f840-b6b4-436f-ae28-66651072b30b'	System	11 Aug 2020 02:42:48
User entered 'No (N)'	System	11 Aug 2020 02:42:48

FDA-CBER-2022-1614-0505358

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:42:19', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ecb5f840-b6b4-436f-ae28-66651072b30b'	System	11 Aug 2020 02:42:48
User entered 'No (N)'	System	11 Aug 2020 02:42:48

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:42:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ecb5f840-b6b4-436f-ae28-66651072b30b'	System	11 Aug 2020 02:42:48
User entered 'None (1)'	System	11 Aug 2020 02:42:48

FDA-CBER-2022-1614-0505360

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:42:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ecb5f840-b6b4-436f-ae28-66651072b30b'	System	11 Aug 2020 02:42:48
User entered '10 Aug 2020 19:42'	System	11 Aug 2020 02:42:48

FDA-CBER-2022-1614-0505361

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 17:46'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505362

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505363

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 2'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:42:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '561000b2-17d6-4272-873d-77d5e5f24dc4'	System	12 Aug 2020 03:43:04
User entered 'None (1)'	System	12 Aug 2020 03:43:04

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:42:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '561000b2-17d6-4272-873d-77d5e5f24dc4'	System	12 Aug 2020 03:43:04
User entered 'No (N)'	System	12 Aug 2020 03:43:04

FDA-CBER-2022-1614-0505366

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:42:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '561000b2-17d6-4272-873d-77d5e5f24dc4'	System	12 Aug 2020 03:43:04
User entered 'No (N)'	System	12 Aug 2020 03:43:04

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:42:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '561000b2-17d6-4272-873d-77d5e5f24dc4'	System	12 Aug 2020 03:43:04
User entered 'None (1)'	System	12 Aug 2020 03:43:04

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '561000b2-17d6-4272-873d-77d5e5f24dc4'	System	12 Aug 2020 03:43:04
User entered '11 Aug 2020 20:43'	System	12 Aug 2020 03:43:04

FDA-CBER-2022-1614-0505369

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505370

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505371

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 3'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd1a0ca36-5140-4ac2-82a6-be14879e4045'	System	13 Aug 2020 01:39:31
User entered 'None (1)'	System	13 Aug 2020 01:39:31

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd1a0ca36-5140-4ac2-82a6-be14879e4045'	System	13 Aug 2020 01:39:31
User entered 'No (N)'	System	13 Aug 2020 01:39:31

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd1a0ca36-5140-4ac2-82a6-be14879e4045'	System	13 Aug 2020 01:39:31
User entered 'No (N)'	System	13 Aug 2020 01:39:31

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd1a0ca36-5140-4ac2-82a6-be14879e4045'	System	13 Aug 2020 01:39:31
User entered 'None (1)'	System	13 Aug 2020 01:39:31

FDA-CBER-2022-1614-0505376

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd1a0ca36-5140-4ac2-82a6-be14879e4045'	System	13 Aug 2020 01:39:31
User entered '12 Aug 2020 18:39'	System	13 Aug 2020 01:39:31

FDA-CBER-2022-1614-0505377

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505378

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505379

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 4'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:01', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76509a7d-4d70-445a-9b2f-159a92b3defc'	System	14 Aug 2020 04:15:38
User entered 'None (1)'	System	14 Aug 2020 04:15:38

FDA-CBER-2022-1614-0505381

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:05', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76509a7d-4d70-445a-9b2f-159a92b3defc'	System	14 Aug 2020 04:15:38
User entered 'No (N)'	System	14 Aug 2020 04:15:38

FDA-CBER-2022-1614-0505382

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:08', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76509a7d-4d70-445a-9b2f-159a92b3defc'	System	14 Aug 2020 04:15:38
User entered 'No (N)'	System	14 Aug 2020 04:15:38

FDA-CBER-2022-1614-0505383

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76509a7d-4d70-445a-9b2f-159a92b3defc'	System	14 Aug 2020 04:15:38
User entered 'None (1)'	System	14 Aug 2020 04:15:38

FDA-CBER-2022-1614-0505384

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76509a7d-4d70-445a-9b2f-159a92b3defc'	System	14 Aug 2020 04:15:38
User entered '13 Aug 2020 21:15'	System	14 Aug 2020 04:15:38

FDA-CBER-2022-1614-0505385

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505386

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 5'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '56a3174a-bb3e-4534-b614-e5dcd8f54d26'	System	15 Aug 2020 04:00:43
User entered 'None (1)'	System	15 Aug 2020 04:00:43

FDA-CBER-2022-1614-0505389

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T20:59:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '56a3174a-bb3e-4534-b614-e5dcd8f54d26'	System	15 Aug 2020 04:00:43
User entered 'No (N)'	System	15 Aug 2020 04:00:43

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '56a3174a-bb3e-4534-b614-e5dcd8f54d26'	System	15 Aug 2020 04:00:43
User entered 'No (N)'	System	15 Aug 2020 04:00:43

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '56a3174a-bb3e-4534-b614-e5dcd8f54d26'	System	15 Aug 2020 04:00:43
User entered 'None (1)'	System	15 Aug 2020 04:00:43

FDA-CBER-2022-1614-0505392

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '56a3174a-bb3e-4534-b614-e5dcd8f54d26'	System	15 Aug 2020 04:00:43
User entered '14 Aug 2020 21:00'	System	15 Aug 2020 04:00:43

FDA-CBER-2022-1614-0505393

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505394

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505395

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 6'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6eccf71a-f87c-461d-bc3e-cf7c825c0a60'	System	16 Aug 2020 03:32:15
User entered 'None (1)'	System	16 Aug 2020 03:32:15

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6eccf71a-f87c-461d-bc3e-cf7c825c0a60'	System	16 Aug 2020 03:32:15
User entered 'No (N)'	System	16 Aug 2020 03:32:15

FDA-CBER-2022-1614-0505398

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:31:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6eccf71a-f87c-461d-bc3e-cf7c825c0a60'	System	16 Aug 2020 03:32:15
User entered 'No (N)'	System	16 Aug 2020 03:32:15

FDA-CBER-2022-1614-0505399

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6eccf71a-f87c-461d-bc3e-cf7c825c0a60'	System	16 Aug 2020 03:32:15
User entered 'None (1)'	System	16 Aug 2020 03:32:15

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6eccf71a-f87c-461d-bc3e-cf7c825c0a60'	System	16 Aug 2020 03:32:15
User entered '15 Aug 2020 20:32'	System	16 Aug 2020 03:32:15

FDA-CBER-2022-1614-0505401

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505402

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 7'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:20', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58dfbacd-bd04-4fa9-b2f6-9d1d11ebde6e'	System	17 Aug 2020 03:06:39
User entered 'None (1)'	System	17 Aug 2020 03:06:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58dfbacd-bd04-4fa9-b2f6-9d1d11ebde6e'	System	17 Aug 2020 03:06:39
User entered 'No (N)'	System	17 Aug 2020 03:06:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58dfbacd-bd04-4fa9-b2f6-9d1d11ebde6e'	System	17 Aug 2020 03:06:39
User entered 'No (N)'	System	17 Aug 2020 03:06:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58dfbacd-bd04-4fa9-b2f6-9d1d11ebde6e'	System	17 Aug 2020 03:06:39
User entered 'None (1)'	System	17 Aug 2020 03:06:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58dfbacd-bd04-4fa9-b2f6-9d1d11ebde6e'	System	17 Aug 2020 03:06:39
User entered '16 Aug 2020 20:06'	System	17 Aug 2020 03:06:39

US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

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US3112173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:38:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:38:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

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US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

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US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'None (0)'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered 'No (N)'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T14:39:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c62f32d-0da7-4d98-b277-7223083041bd'	System	10 Aug 2020 21:39:36
User entered '10 Aug 2020 14:39'	System	10 Aug 2020 21:39:36

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 14:21'	System	10 Aug 2020 21:08:50

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US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 16:51'	System	10 Aug 2020 21:08:50

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US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:42:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:08', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

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US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:19', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'None (0)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered 'No (N)'	System	11 Aug 2020 02:43:48

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-10T19:43:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5e1a7b97-0e5d-49d6-aea1-222e37583365'	System	11 Aug 2020 02:43:48
User entered '10 Aug 2020 19:43'	System	11 Aug 2020 02:43:48

FDA-CBER-2022-1614-0505431

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Aug 2020 17:46'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505432

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505433

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 2'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505435

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505436

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505437

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505439

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:39', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'None (0)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505440

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered 'No (N)'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505441

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-11T20:43:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '182fcfdd-d669-4a7c-b82d-9848bba06402'	System	12 Aug 2020 03:44:00
User entered '11 Aug 2020 20:43'	System	12 Aug 2020 03:44:00

FDA-CBER-2022-1614-0505442

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505443

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505444

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 3'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:35', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'None (0)'	System	13 Aug 2020 01:40:08

FDA-CBER-2022-1614-0505451

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:39:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered 'No (N)'	System	13 Aug 2020 01:40:08

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-12T18:40:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2559138d-41d2-4bc5-9c39-1fba73571421'	System	13 Aug 2020 01:40:08
User entered '12 Aug 2020 18:40'	System	13 Aug 2020 01:40:08

FDA-CBER-2022-1614-0505453

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505454

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505455

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 4'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505457

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505458

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505459

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:15:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505460

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:16:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505461

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:16:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'None (0)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505462

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:16:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered 'No (N)'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505463

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-13T21:16:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b16bde1-d9b4-461b-ad74-91a5a5162477'	System	14 Aug 2020 04:16:26
User entered '13 Aug 2020 21:16'	System	14 Aug 2020 04:16:26

FDA-CBER-2022-1614-0505464

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505466

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 5'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505468

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505469

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505470

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:00:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505471

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:01:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505472

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:01:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'None (0)'	System	15 Aug 2020 04:01:24

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:01:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered 'No (N)'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505474

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-14T21:01:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '32ce3d8c-8150-4e18-847a-a8b34a8200c7'	System	15 Aug 2020 04:01:24
User entered '14 Aug 2020 21:01'	System	15 Aug 2020 04:01:24

FDA-CBER-2022-1614-0505475

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505476

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505477

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 6'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505479

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:28', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505481

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505483

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'None (0)'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505484

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered 'No (N)'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505485

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-15T20:32:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c919d15a-e421-4153-9324-0f372dc6b2ee'	System	16 Aug 2020 03:32:56
User entered '15 Aug 2020 20:32'	System	16 Aug 2020 03:32:56

FDA-CBER-2022-1614-0505486

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505487

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505488

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 7'	System	10 Aug 2020 21:08:50

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

FDA-CBER-2022-1614-0505490

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

FDA-CBER-2022-1614-0505494

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'None (0)'	System	17 Aug 2020 03:07:11

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:06:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered 'No (N)'	System	17 Aug 2020 03:07:11

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-16T20:07:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '89c86a67-553a-49ad-8c52-35f0196c42b2'	System	17 Aug 2020 03:07:11
User entered '16 Aug 2020 20:07'	System	17 Aug 2020 03:07:11

FDA-CBER-2022-1614-0505497

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505498

US3112173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:50

FDA-CBER-2022-1614-0505499

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	16 Aug 2020 03:31:44
User entered 'Day 8'	System	16 Aug 2020 03:31:44

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:01:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0c5cf665-1985-4b58-a479-72e6afbb7510'	System	18 Aug 2020 06:01:18
User entered 'No (N)'	System	18 Aug 2020 06:01:18

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-17T23:01:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0c5cf665-1985-4b58-a479-72e6afbb7510'	System	18 Aug 2020 06:01:18
User entered '17 Aug 2020 23:01'	System	18 Aug 2020 06:01:18

FDA-CBER-2022-1614-0505502

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505503

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 03:31:44

FDA-CBER-2022-1614-0505504

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	17 Aug 2020 03:06:15
User entered 'Day 9'	System	17 Aug 2020 03:06:15

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df762c6f-b238-4591-90c2-32362211d4ed'	System	19 Aug 2020 04:24:58
User entered 'No (N)'	System	19 Aug 2020 04:24:58

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-18T21:24:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'df762c6f-b238-4591-90c2-32362211d4ed'	System	19 Aug 2020 04:24:58
User entered '18 Aug 2020 21:24'	System	19 Aug 2020 04:24:58

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505508

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 03:06:15

FDA-CBER-2022-1614-0505509

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Aug 2020 06:01:08
User entered 'Day 10'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505510

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '482f247a-b6a8-4ae6-9664-f094d2ec384f'	System	20 Aug 2020 04:04:20
User entered 'No (N)'	System	20 Aug 2020 04:04:20

FDA-CBER-2022-1614-0505511

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-19T21:04:19', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '482f247a-b6a8-4ae6-9664-f094d2ec384f'	System	20 Aug 2020 04:04:20
User entered '19 Aug 2020 21:04'	System	20 Aug 2020 04:04:20

FDA-CBER-2022-1614-0505512

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505513

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 06:01:08

FDA-CBER-2022-1614-0505514

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	19 Aug 2020 04:24:46
User entered 'Day 11'	System	19 Aug 2020 04:24:46

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:06:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '37e1921e-5db6-487b-981e-65e9cac8ba97'	System	21 Aug 2020 04:06:13
User entered 'No (N)'	System	21 Aug 2020 04:06:13

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-20T21:06:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '37e1921e-5db6-487b-981e-65e9cac8ba97'	System	21 Aug 2020 04:06:13
User entered '20 Aug 2020 21:06'	System	21 Aug 2020 04:06:13

FDA-CBER-2022-1614-0505517

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505518

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 04:24:46

FDA-CBER-2022-1614-0505519

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	20 Aug 2020 04:04:15
User entered 'Day 12'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505520

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '922baebb-c437-4ce5-980d-4ef6796572bf'	System	22 Aug 2020 04:29:49
User entered 'No (N)'	System	22 Aug 2020 04:29:49

FDA-CBER-2022-1614-0505521

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-21T21:29:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '922baebb-c437-4ce5-980d-4ef6796572bf'	System	22 Aug 2020 04:29:49
User entered '21 Aug 2020 21:29'	System	22 Aug 2020 04:29:49

FDA-CBER-2022-1614-0505522

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505523

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 04:04:15

FDA-CBER-2022-1614-0505524

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	21 Aug 2020 04:05:58
User entered 'Day 13'	System	21 Aug 2020 04:05:58

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:55:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '448e03cb-cf35-4b7d-8cdf-528fbee7aa4b'	System	23 Aug 2020 02:55:15
User entered 'No (N)'	System	23 Aug 2020 02:55:15

FDA-CBER-2022-1614-0505526

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-22T19:55:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '448e03cb-cf35-4b7d-8cdf-528fbee7aa4b'	System	23 Aug 2020 02:55:15
User entered '22 Aug 2020 19:55'	System	23 Aug 2020 02:55:15

FDA-CBER-2022-1614-0505527

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505528

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 04:05:58

FDA-CBER-2022-1614-0505529

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	22 Aug 2020 04:29:39
User entered 'Day 14'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505530

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:18:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c6a160e7-a671-4001-9080-07ab68ebc17d'	System	24 Aug 2020 04:19:04
User entered 'No (N)'	System	24 Aug 2020 04:19:04

FDA-CBER-2022-1614-0505531

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-23T21:19:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c6a160e7-a671-4001-9080-07ab68ebc17d'	System	24 Aug 2020 04:19:04
User entered '23 Aug 2020 21:19'	System	24 Aug 2020 04:19:04

FDA-CBER-2022-1614-0505532

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 04:29:39

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 04:29:39

FDA-CBER-2022-1614-0505534

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	23 Aug 2020 02:55:08
User entered 'Day 15'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505535

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:28:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3f355f0d-e2e6-48d4-b400-130c675622bd'	System	25 Aug 2020 01:28:47
User entered 'Yes (Y)'	System	25 Aug 2020 01:28:47

FDA-CBER-2022-1614-0505536

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-24T18:28:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3f355f0d-e2e6-48d4-b400-130c675622bd'	System	25 Aug 2020 01:28:47
User entered '24 Aug 2020 18:28'	System	25 Aug 2020 01:28:47

FDA-CBER-2022-1614-0505537

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505538

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:55:08

FDA-CBER-2022-1614-0505539

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	24 Aug 2020 04:18:57
User entered 'Day 16'	System	24 Aug 2020 04:18:57

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:05:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fcd651c5-3a8a-49e7-8417-9f1e5bbd5fda'	System	26 Aug 2020 00:05:27
User entered 'Yes (Y)'	System	26 Aug 2020 00:05:27

FDA-CBER-2022-1614-0505541

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-08-25T17:05:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fcd651c5-3a8a-49e7-8417-9f1e5bbd5fda'	System	26 Aug 2020 00:05:27
User entered '25 Aug 2020 17:05'	System	26 Aug 2020 00:05:27

FDA-CBER-2022-1614-0505542

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505543

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 04:18:57

FDA-CBER-2022-1614-0505544

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	25 Aug 2020 01:27:41
User entered 'Day 17'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505545

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505547

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505548

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 01:27:41

FDA-CBER-2022-1614-0505549

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	26 Aug 2020 00:04:46
User entered 'Day 18'	System	26 Aug 2020 00:04:46

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505552

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505553

US3112173
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 00:04:46

FDA-CBER-2022-1614-0505554

US3112173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 00:35:17

US3112173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:41
User entered '17 Aug 2020'	Karen Mylerberg (b) (4)	26 Aug 2020 00:35:17

US3112173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karen Mylerberg (b) (4)	26 Aug 2020 00:35:17

US3112173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:41
User entered 'Could not reach subject'	Karen Mylerberg (b) (4)	26 Aug 2020 00:35:17

FDA-CBER-2022-1614-0505558

US3112173
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:31:44
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:41:15
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	26 Aug 2020 00:35:24

US3112173
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	26 Aug 2020 00:35:24

US3112173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:54
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 00:36:34

US3112173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:54
User entered '25 Aug 2020'	Karen Mylerberg (b) (4)	26 Aug 2020 00:36:34

FDA-CBER-2022-1614-0505562

US3112173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:54
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	26 Aug 2020 00:36:34

US3112173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:31:54
User entered empty.	Karen Mylerberg (b) (4)	26 Aug 2020 00:36:34

US3112173
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:32:41
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	26 Aug 2020 00:36:40

US3112173
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	26 Aug 2020 00:36:40

US3112173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:31:45
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 19:07:38

US3112173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:31:45
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 19:07:38

US3112173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:31:45
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 19:07:38

FDA-CBER-2022-1614-0505569

US3112173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:31:45
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 19:07:38

FDA-CBER-2022-1614-0505570

US3112173
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:32:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:14:10

FDA-CBER-2022-1614-0505571

US3112173
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	14 Sep 2020 16:14:10

US3112173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:53:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:14:47

FDA-CBER-2022-1614-0505573

US3112173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:53:29
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:14:47

FDA-CBER-2022-1614-0505574

US3112173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:53:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 16:14:47

FDA-CBER-2022-1614-0505575

US3112173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'VISIT2'	System	14 Sep 2020 16:14:47

FDA-CBER-2022-1614-0505576

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505577

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '10:33'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505580

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Sep 2020 10:33'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505581

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '98.0' F	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505582

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505583

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505584

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '86'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505585

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505586

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '14'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505587

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505588

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '99'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505590

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:31
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:26:57
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per investigator NCS' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 16:59:40
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:50:42
User entered '58'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505591

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505592

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505593

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '12:36'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505596

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Sep 2020 12:36'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505597

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '98.0' F	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505598

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505599

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505600

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:31
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	29 Sep 2020 17:00:08
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	29 Sep 2020 17:00:08
User entered '75' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:00:08
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 16:16:12
User entered '756'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505601

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505602

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '16'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505603

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505604

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:31
User entered '115'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505606

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:31
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:27:05
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per investigator NCS' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	29 Sep 2020 17:00:24
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:50:42
User entered '59'	(b) (4), (b) (6)	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505607

US3112173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	14 Sep 2020 16:16:12

FDA-CBER-2022-1614-0505608

US3112173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:18:28

US3112173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:42
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:18:28

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
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)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered '12:01'	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Sep 2020 12:01'	System	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered 'ONCE'	System	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:16:53

US3112173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:17:15

US3112173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:08
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:17:15

FDA-CBER-2022-1614-0505622

US3112173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:08
User entered '10:55'	(b) (4), (b) (6)	14 Sep 2020 16:17:15

FDA-CBER-2022-1614-0505623

US3112173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Sep 2020 10:55'	System	14 Sep 2020 16:17:15

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:23
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:23
User entered '10:45'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

FDA-CBER-2022-1614-0505628

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '10 Sep 2020 10:45'	System	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:23
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 16:17:32

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:23
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 16:17:32

FDA-CBER-2022-1614-0505632

US3112173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered empty.	System	14 Sep 2020 16:17:32

FDA-CBER-2022-1614-0505633

US3112173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 16:18:11

FDA-CBER-2022-1614-0505634

US3112173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	14 Sep 2020 16:18:11

FDA-CBER-2022-1614-0505635

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505637

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505638

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505639

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505640

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505641

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505642

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 12:21'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 14:51'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505644

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505646

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505647

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505648

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505650

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505651

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 15:46'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 2'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505655

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505656

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505657

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505658

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505659

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505660

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505661

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 3'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505664

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505665

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505667

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505668

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505669

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505670

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 4'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:51:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered 'Yes (Y)'	System	14 Sep 2020 17:53:03

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:52:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered '98.6'	System	14 Sep 2020 17:53:03

FDA-CBER-2022-1614-0505674

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:52:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered 'Yes (Y)'	System	14 Sep 2020 17:53:03

FDA-CBER-2022-1614-0505675

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:17:37
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 17:53:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:52:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered '1'	System	14 Sep 2020 17:53:03

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:52:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered '0'	System	14 Sep 2020 17:53:03

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:52:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fdec16ab-a714-4999-aa2a-2e551d7e8063'	System	14 Sep 2020 17:53:03
User entered '14 Sep 2020 10:52'	System	14 Sep 2020 17:53:03

FDA-CBER-2022-1614-0505678

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505680

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 5'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered 'Yes (Y)'	System	14 Sep 2020 23:58:51

FDA-CBER-2022-1614-0505682

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered '97.6'	System	14 Sep 2020 23:58:51

FDA-CBER-2022-1614-0505683

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:39', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered 'Yes (Y)'	System	14 Sep 2020 23:58:51

FDA-CBER-2022-1614-0505684

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:17:44
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 23:58:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered '1'	System	14 Sep 2020 23:58:51

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered '0'	System	14 Sep 2020 23:58:51

FDA-CBER-2022-1614-0505686

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0fbc63ee-98a7-44ad-922b-bc8291949c30'	System	14 Sep 2020 23:58:51
User entered '14 Sep 2020 16:58'	System	14 Sep 2020 23:58:51

FDA-CBER-2022-1614-0505687

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505689

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 6'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:00:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered 'Yes (Y)'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505691

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:00:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered '97.8'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505692

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:00:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered 'Yes (Y)'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505693

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:17:49
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 19:01:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered '1'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505694

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered '0'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505695

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd8d7449d-b1d4-4c83-94e7-37502837ec31'	System	15 Sep 2020 19:01:12
User entered '15 Sep 2020 12:01'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0505696

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505697

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505698

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 7'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered 'Yes (Y)'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505700

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered '99.0'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505701

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered 'Yes (Y)'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505702

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:17:54
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 19:32:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered '1'	System	16 Sep 2020 19:32:49

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered '0'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505704

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbfd2db5-0d12-4dd5-91df-c37fd3ae5c7c'	System	16 Sep 2020 19:32:49
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 19:32:49

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505707

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	15 Sep 2020 19:01:12
User entered 'Day 8'	System	15 Sep 2020 19:01:12

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:30:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered 'Yes (Y)'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505709

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:30:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered '97.7'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505710

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:01', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered 'Yes (Y)'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505711

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:17:59
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Sep 2020 10:31:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:05', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered '1'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505712

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:05', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered '0'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505713

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5c855c18-a96f-4507-acd8-d4812b49810a'	System	18 Sep 2020 10:31:49
User entered '18 Sep 2020 03:31'	System	18 Sep 2020 10:31:49

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:01:12

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:01:12

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	16 Sep 2020 19:32:49
User entered 'Day 9'	System	16 Sep 2020 19:32:49

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T13:59:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered 'Yes (Y)'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505718

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T13:59:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered '98.2'	System	18 Sep 2020 21:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T13:59:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered 'Yes (Y)'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505720

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:04
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:48:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Sep 2020 21:00:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T13:59:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered '1'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505721

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T13:59:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered '0'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505722

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T14:00:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd976e919-98a6-4372-ad09-2cb1866270ad'	System	18 Sep 2020 21:00:11
User entered '18 Sep 2020 14:00'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505723

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505724

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0505725

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Sep 2020 10:31:49
User entered 'Day 10'	System	18 Sep 2020 10:31:49

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered 'Yes (Y)'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505727

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered '97.4'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505728

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered 'Yes (Y)'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505729

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:09
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:49:04
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Sep 2020 19:08:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered '1'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505730

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered '0'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505731

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82e74fea-18bb-48cf-a168-66555440d229'	System	19 Sep 2020 19:08:41
User entered '19 Sep 2020 12:08'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505732

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505733

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0505734

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Sep 2020 21:00:11
User entered 'Day 11'	System	18 Sep 2020 21:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered 'Yes (Y)'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505736

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered '97.7'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505737

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered 'Yes (Y)'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505738

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:14
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:49:13
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	20 Sep 2020 19:03:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered '1'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505739

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered '0'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505740

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd9ae8f5c-ed86-4609-a776-904ba7e5a4aa'	System	20 Sep 2020 19:03:40
User entered '20 Sep 2020 12:03'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505741

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505742

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0505743

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	19 Sep 2020 19:08:41
User entered 'Day 12'	System	19 Sep 2020 19:08:41

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T12:59:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered 'Yes (Y)'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505745

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T12:59:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered '98.8'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505746

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T12:59:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered 'Yes (Y)'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505747

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:19
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:49:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Sep 2020 20:00:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T12:59:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered '1'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505748

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T12:59:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered '0'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505749

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T13:00:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'de7581ff-2f5c-4ca4-aa33-464ef77b6597'	System	21 Sep 2020 20:00:11
User entered '21 Sep 2020 13:00'	System	21 Sep 2020 20:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505751

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0505752

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	20 Sep 2020 19:03:40
User entered 'Day 13'	System	20 Sep 2020 19:03:40

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:36:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered 'Yes (Y)'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505754

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:36:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered '98.0'	System	22 Sep 2020 23:37:10

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:36:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered 'Yes (Y)'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505756

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:23
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:50:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Sep 2020 23:37:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:36:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered '1'	System	22 Sep 2020 23:37:10

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:36:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered '0'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505758

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:37:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c0d3be92-6a8e-4f41-a383-0cfb2451a58b'	System	22 Sep 2020 23:37:10
User entered '22 Sep 2020 16:37'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505759

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505760

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0505761

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	21 Sep 2020 20:00:11
User entered 'Day 14'	System	21 Sep 2020 20:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered 'Yes (Y)'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505763

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered '97.7'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505764

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:11', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered 'Yes (Y)'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505765

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:31
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:50:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Sep 2020 19:14:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered '1'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505766

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered '0'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505767

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fca4df6b-39ce-4be3-9416-83176f69b85b'	System	23 Sep 2020 19:14:26
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505768

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505769

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0505770

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	22 Sep 2020 23:37:10
User entered 'Day 15'	System	22 Sep 2020 23:37:10

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered 'Yes (Y)'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505772

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered '97.9'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505773

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered 'Yes (Y)'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505774

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:36
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:50:33
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	24 Sep 2020 20:53:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered '1'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505775

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered '0'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505776

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:53:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '94988aea-b474-4696-97da-87170f9f9440'	System	24 Sep 2020 20:53:56
User entered '24 Sep 2020 13:53'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505777

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505778

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 23:37:10

FDA-CBER-2022-1614-0505779

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	23 Sep 2020 19:14:26
User entered 'Day 16'	System	23 Sep 2020 19:14:26

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:42:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered 'Yes (Y)'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505781

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:42:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered '98.0'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505782

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:42:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered 'Yes (Y)'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505783

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' canceled (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 19:43:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:42:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered '1'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505784

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:42:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered '0'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505785

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:43:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '87bf2b15-8976-41c3-8a58-1535918a4f74'	System	25 Sep 2020 19:43:05
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505786

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505787

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:14:26

FDA-CBER-2022-1614-0505788

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	24 Sep 2020 20:53:56
User entered 'Day 17'	System	24 Sep 2020 20:53:56

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:13:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered 'Yes (Y)'	System	26 Sep 2020 19:14:07

FDA-CBER-2022-1614-0505790

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:13:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered '98.2'	System	26 Sep 2020 19:14:07

FDA-CBER-2022-1614-0505791

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:13:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered 'Yes (Y)'	System	26 Sep 2020 19:14:07

FDA-CBER-2022-1614-0505792

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' canceled (Site from System).	(b) (4), (b) (6)	28 Sep 2020 04:18:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Sep 2020 19:14:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:13:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered '1'	System	26 Sep 2020 19:14:07

FDA-CBER-2022-1614-0505793

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:13:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered '0'	System	26 Sep 2020 19:14:07

FDA-CBER-2022-1614-0505794

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:14:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c353ecf7-90f4-4f64-9a35-9749976fc3e8'	System	26 Sep 2020 19:14:07
User entered '26 Sep 2020 12:14'	System	26 Sep 2020 19:14:07

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505796

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 20:53:56

FDA-CBER-2022-1614-0505797

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	25 Sep 2020 19:43:05
User entered 'Day 18'	System	25 Sep 2020 19:43:05

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered 'Yes (Y)'	System	27 Sep 2020 19:50:52

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered '98.3'	System	27 Sep 2020 19:50:52

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered 'Yes (Y)'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505801

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:05
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:28:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Sep 2020 19:50:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered '1'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505802

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered '0'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505803

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '31e09f16-f486-4141-bcab-7ca2d61a849e'	System	27 Sep 2020 19:50:52
User entered '27 Sep 2020 12:50'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505804

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:43:05

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:43:05

FDA-CBER-2022-1614-0505806

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	26 Sep 2020 19:14:07
User entered 'Day 19'	System	26 Sep 2020 19:14:07

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered 'Yes (Y)'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505808

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered '98.3'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505809

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered 'Yes (Y)'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505810

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:10
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:28:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	28 Sep 2020 20:10:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered '1'	System	28 Sep 2020 20:10:59

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered '0'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505812

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:10:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '42fcf3a6-f22d-43e1-860c-008afbed3a83'	System	28 Sep 2020 20:10:59
User entered '28 Sep 2020 13:10'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505813

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:14:07

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:14:07

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	27 Sep 2020 19:50:52
User entered 'Day 20'	System	27 Sep 2020 19:50:52

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered 'Yes (Y)'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505817

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered '98.3'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505818

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered 'Yes (Y)'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505819

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:23
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:28:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Sep 2020 20:18:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered '1'	System	29 Sep 2020 20:18:44

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered '0'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505821

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '642851be-1cd3-4288-b7e1-fed622ecb18f'	System	29 Sep 2020 20:18:44
User entered '29 Sep 2020 13:18'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505822

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505823

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 19:50:52

FDA-CBER-2022-1614-0505824

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	28 Sep 2020 20:10:59
User entered 'Day 21'	System	28 Sep 2020 20:10:59

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:20', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered 'Yes (Y)'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505826

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered '98.0'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505827

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered 'Yes (Y)'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505828

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:31
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:28:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Sep 2020 19:46:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered '1'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505829

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered '0'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505830

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:41', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '36be3fe3-cb97-4d31-ae6c-478db4a0db3c'	System	30 Sep 2020 19:46:45
User entered '30 Sep 2020 12:46'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505831

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505832

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 20:10:59

FDA-CBER-2022-1614-0505833

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	29 Sep 2020 20:18:44
User entered 'Day 22'	System	29 Sep 2020 20:18:44

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:11', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered 'Yes (Y)'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505835

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered '98.6'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505836

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:19', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered 'Yes (Y)'	System	01 Oct 2020 19:09:37

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:37
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:00
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	01 Oct 2020 19:09:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered '1'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505838

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered '0'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505839

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '21aca8e0-2b16-452c-ba76-fe2cbd635e12'	System	01 Oct 2020 19:09:37
User entered '01 Oct 2020 12:09'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505840

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505841

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0505842

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	30 Sep 2020 19:46:45
User entered 'Day 23'	System	30 Sep 2020 19:46:45

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered 'Yes (Y)'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505844

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered '98.8'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505845

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered 'Yes (Y)'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505846

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:42
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Oct 2020 16:38:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered '1'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505847

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered '0'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505848

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:37', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '66879582-aaa1-4985-a6f8-7556248b39c8'	System	03 Oct 2020 16:38:39
User entered '03 Oct 2020 09:38'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505849

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505850

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0505851

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	01 Oct 2020 19:09:37
User entered 'Day 24'	System	01 Oct 2020 19:09:37

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:58:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered 'Yes (Y)'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505853

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:58:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered '97.9'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505854

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:58:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered 'Yes (Y)'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505855

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:48
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	03 Oct 2020 19:59:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:58:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered '1'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505856

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:58:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered '0'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505857

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:59:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fd2ceeb4-bab0-40ec-8385-a3eea24b7d69'	System	03 Oct 2020 19:59:05
User entered '03 Oct 2020 12:59'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505858

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:09:37

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0505860

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	03 Oct 2020 16:38:39
User entered 'Day 25'	System	03 Oct 2020 16:38:39

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:07:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered 'Yes (Y)'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505862

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:07:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered '98.1'	System	04 Oct 2020 19:08:12

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered 'Yes (Y)'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505864

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:53
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 19:08:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered '1'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505865

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered '0'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505866

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '4d63f87f-fd7e-41c4-8984-be8e86c247fc'	System	04 Oct 2020 19:08:12
User entered '04 Oct 2020 12:08'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505867

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505868

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0505869

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	03 Oct 2020 19:59:05
User entered 'Day 26'	System	03 Oct 2020 19:59:05

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered 'Yes (Y)'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505871

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered '98.8'	System	05 Oct 2020 19:04:25

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered 'Yes (Y)'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505873

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:10:59
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Oct 2020 19:04:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered '1'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505874

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered '0'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505875

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b6dad851-5166-4fce-a85d-47c7ea978101'	System	05 Oct 2020 19:04:25
User entered '05 Oct 2020 12:04'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505876

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505877

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0505878

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	04 Oct 2020 19:08:12
User entered 'Day 27'	System	04 Oct 2020 19:08:12

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered 'Yes (Y)'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505880

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered '98.2'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505881

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered 'Yes (Y)'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505882

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:11:04
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Oct 2020 19:10:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered '1'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505883

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered '0'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505884

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:10:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5a240b6-e9b7-4783-b02a-ea98abd1a238'	System	06 Oct 2020 19:10:58
User entered '06 Oct 2020 12:10'	System	06 Oct 2020 19:10:58

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505886

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0505887

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	05 Oct 2020 19:04:25
User entered 'Day 28'	System	05 Oct 2020 19:04:25

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered 'Yes (Y)'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505889

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered '97.8'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505890

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered 'Yes (Y)'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505891

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:11:10
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Oct 2020 20:44:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered '1'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505892

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:29', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered '0'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505893

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '032eb948-b710-4257-88f0-124f83dc9c7d'	System	07 Oct 2020 20:44:39
User entered '07 Oct 2020 13:44'	System	07 Oct 2020 20:44:39

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505895

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0505896

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	06 Oct 2020 19:10:58
User entered 'Day 29'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505897

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered 'Yes (Y)'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505898

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered '98.2'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505899

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered 'Yes (Y)'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505900

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:11:16
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Oct 2020 19:02:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered '1'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505901

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered '0'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505902

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2d6888d9-7f76-44d7-885a-bb18773a4466'	System	08 Oct 2020 19:02:56
User entered '08 Oct 2020 12:02'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505903

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505904

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0505905

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	07 Oct 2020 20:44:39
User entered 'Day 30'	System	07 Oct 2020 20:44:39

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '34761e25-87f9-43b0-83b7-dcfa0a34b621'	System	09 Oct 2020 19:25:28
User entered 'No (N)'	System	09 Oct 2020 19:25:28

FDA-CBER-2022-1614-0505907

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '34761e25-87f9-43b0-83b7-dcfa0a34b621'	System	09 Oct 2020 19:25:28
User entered 'Yes (Y)'	System	09 Oct 2020 19:25:28

FDA-CBER-2022-1614-0505908

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:11:22
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:29:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Oct 2020 19:25:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '34761e25-87f9-43b0-83b7-dcfa0a34b621'	System	09 Oct 2020 19:25:28
User entered '1'	System	09 Oct 2020 19:25:28

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:23', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '34761e25-87f9-43b0-83b7-dcfa0a34b621'	System	09 Oct 2020 19:25:28
User entered '0'	System	09 Oct 2020 19:25:28

FDA-CBER-2022-1614-0505910

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '34761e25-87f9-43b0-83b7-dcfa0a34b621'	System	09 Oct 2020 19:25:28
User entered '09 Oct 2020 12:25'	System	09 Oct 2020 19:25:28

FDA-CBER-2022-1614-0505911

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505912

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0505913

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	08 Oct 2020 19:02:56
User entered 'Day 31'	System	08 Oct 2020 19:02:56

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:16:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76f86cb0-b8a4-480a-aee6-3575f43221db'	System	10 Oct 2020 19:17:09
User entered 'No (N)'	System	10 Oct 2020 19:17:09

FDA-CBER-2022-1614-0505915

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:16:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76f86cb0-b8a4-480a-aee6-3575f43221db'	System	10 Oct 2020 19:17:09
User entered 'Yes (Y)'	System	10 Oct 2020 19:17:09

FDA-CBER-2022-1614-0505916

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:11:32
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	16 Oct 2020 17:30:03
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	10 Oct 2020 19:17:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:01', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76f86cb0-b8a4-480a-aee6-3575f43221db'	System	10 Oct 2020 19:17:09
User entered '1'	System	10 Oct 2020 19:17:09

FDA-CBER-2022-1614-0505917

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:01', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76f86cb0-b8a4-480a-aee6-3575f43221db'	System	10 Oct 2020 19:17:09
User entered '0'	System	10 Oct 2020 19:17:09

FDA-CBER-2022-1614-0505918

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:05', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '76f86cb0-b8a4-480a-aee6-3575f43221db'	System	10 Oct 2020 19:17:09
User entered '10 Oct 2020 12:17'	System	10 Oct 2020 19:17:09

FDA-CBER-2022-1614-0505919

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505920

US3112173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0505921

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505922

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505923

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505924

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505925

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505926

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505927

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505928

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505929

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 12:21'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505930

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 14:51'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505931

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505932

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505933

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505934

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505935

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505936

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505937

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505938

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505939

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 15:46'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505940

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505941

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 2'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505943

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505944

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505945

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505946

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505947

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505948

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505949

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505951

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 3'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505952

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505953

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505954

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505955

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505956

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505957

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505958

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505959

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505961

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 4'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82b4a9a1-9948-4cec-b87c-6a885dc71ac5'	System	14 Sep 2020 17:53:39
User entered 'None (1)'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0505963

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82b4a9a1-9948-4cec-b87c-6a885dc71ac5'	System	14 Sep 2020 17:53:39
User entered 'No (N)'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0505964

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82b4a9a1-9948-4cec-b87c-6a885dc71ac5'	System	14 Sep 2020 17:53:39
User entered 'No (N)'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0505965

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82b4a9a1-9948-4cec-b87c-6a885dc71ac5'	System	14 Sep 2020 17:53:39
User entered 'None (1)'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0505966

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '82b4a9a1-9948-4cec-b87c-6a885dc71ac5'	System	14 Sep 2020 17:53:39
User entered '14 Sep 2020 10:53'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0505967

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505969

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 5'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5fce9750-d20d-4113-b0aa-e91e5aab3916'	System	14 Sep 2020 23:59:11
User entered 'None (1)'	System	14 Sep 2020 23:59:11

FDA-CBER-2022-1614-0505971

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:58:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5fce9750-d20d-4113-b0aa-e91e5aab3916'	System	14 Sep 2020 23:59:11
User entered 'No (N)'	System	14 Sep 2020 23:59:11

FDA-CBER-2022-1614-0505972

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5fce9750-d20d-4113-b0aa-e91e5aab3916'	System	14 Sep 2020 23:59:11
User entered 'No (N)'	System	14 Sep 2020 23:59:11

FDA-CBER-2022-1614-0505973

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5fce9750-d20d-4113-b0aa-e91e5aab3916'	System	14 Sep 2020 23:59:11
User entered 'None (1)'	System	14 Sep 2020 23:59:11

FDA-CBER-2022-1614-0505974

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5fce9750-d20d-4113-b0aa-e91e5aab3916'	System	14 Sep 2020 23:59:11
User entered '14 Sep 2020 16:59'	System	14 Sep 2020 23:59:11

FDA-CBER-2022-1614-0505975

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505976

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505977

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 6'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505978

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5bc2010-477d-4648-ad81-f65e687428ba'	System	15 Sep 2020 19:01:43
User entered 'None (1)'	System	15 Sep 2020 19:01:43

FDA-CBER-2022-1614-0505979

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5bc2010-477d-4648-ad81-f65e687428ba'	System	15 Sep 2020 19:01:43
User entered 'No (N)'	System	15 Sep 2020 19:01:43

FDA-CBER-2022-1614-0505980

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5bc2010-477d-4648-ad81-f65e687428ba'	System	15 Sep 2020 19:01:43
User entered 'No (N)'	System	15 Sep 2020 19:01:43

FDA-CBER-2022-1614-0505981

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5bc2010-477d-4648-ad81-f65e687428ba'	System	15 Sep 2020 19:01:43
User entered 'None (1)'	System	15 Sep 2020 19:01:43

FDA-CBER-2022-1614-0505982

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e5bc2010-477d-4648-ad81-f65e687428ba'	System	15 Sep 2020 19:01:43
User entered '15 Sep 2020 12:01'	System	15 Sep 2020 19:01:43

FDA-CBER-2022-1614-0505983

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505984

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505985

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 7'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '52e653a0-448e-40e5-9654-e212ce52262e'	System	16 Sep 2020 19:33:10
User entered 'None (1)'	System	16 Sep 2020 19:33:10

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '52e653a0-448e-40e5-9654-e212ce52262e'	System	16 Sep 2020 19:33:10
User entered 'No (N)'	System	16 Sep 2020 19:33:10

FDA-CBER-2022-1614-0505988

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:32:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '52e653a0-448e-40e5-9654-e212ce52262e'	System	16 Sep 2020 19:33:10
User entered 'No (N)'	System	16 Sep 2020 19:33:10

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '52e653a0-448e-40e5-9654-e212ce52262e'	System	16 Sep 2020 19:33:10
User entered 'None (1)'	System	16 Sep 2020 19:33:10

FDA-CBER-2022-1614-0505990

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '52e653a0-448e-40e5-9654-e212ce52262e'	System	16 Sep 2020 19:33:10
User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:33:10

FDA-CBER-2022-1614-0505991

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505992

US3112173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505993

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0505994

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505995

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505996

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505997

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505998

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0505999

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506000

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506002

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 12:21'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 14:51'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506006

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506007

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506008

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506010

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506011

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Sep 2020 15:46'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 2'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506017

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506018

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506019

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506021

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506022

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506024

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 3'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506028

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506029

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506030

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506032

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506033

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04

FDA-CBER-2022-1614-0506035

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '12 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 4'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:50', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:55', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

FDA-CBER-2022-1614-0506041

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:53:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:54:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

FDA-CBER-2022-1614-0506043

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:54:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'None (0)'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:54:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered 'No (N)'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T10:54:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '803975d1-9082-43ec-8312-3933533a58f1'	System	14 Sep 2020 17:54:37
User entered '14 Sep 2020 10:54'	System	14 Sep 2020 17:54:37

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '13 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

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US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 5'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506050

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506051

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:21', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506052

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506053

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506054

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'None (0)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506055

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered 'No (N)'	System	14 Sep 2020 23:59:46

FDA-CBER-2022-1614-0506056

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-14T16:59:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '17bb5b10-d3ac-41df-ba3c-aa0c13e72f69'	System	14 Sep 2020 23:59:46
User entered '14 Sep 2020 16:59'	System	14 Sep 2020 23:59:46

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 6'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506061

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:43', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506062

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506063

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506064

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506065

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:01:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'None (0)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506066

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:02:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered 'No (N)'	System	15 Sep 2020 19:02:14

FDA-CBER-2022-1614-0506067

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-15T12:02:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '02b7cf80-dee8-4fc6-84fc-e3003a1735f0'	System	15 Sep 2020 19:02:14
User entered '15 Sep 2020 12:02'	System	15 Sep 2020 19:02:14

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

FDA-CBER-2022-1614-0506069

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	14 Sep 2020 16:16:53
User entered 'Day 7'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:11', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:20', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:22', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'None (0)'	System	16 Sep 2020 19:33:38

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered 'No (N)'	System	16 Sep 2020 19:33:38

FDA-CBER-2022-1614-0506078

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-16T12:33:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '856e08c1-1237-4dd5-bbf4-fc4ff533a97a'	System	16 Sep 2020 19:33:38
User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:33:38

FDA-CBER-2022-1614-0506079

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:16:53

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	15 Sep 2020 19:01:12
User entered 'Day 8'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0506082

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a15aeb3d-f91c-43ff-a61f-ac173efae531'	System	18 Sep 2020 10:31:52
User entered 'Yes (Y)'	System	18 Sep 2020 10:31:52

FDA-CBER-2022-1614-0506083

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T03:31:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a15aeb3d-f91c-43ff-a61f-ac173efae531'	System	18 Sep 2020 10:31:52
User entered '18 Sep 2020 03:31'	System	18 Sep 2020 10:31:52

FDA-CBER-2022-1614-0506084

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0506085

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 19:01:12

FDA-CBER-2022-1614-0506086

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	16 Sep 2020 19:32:49
User entered 'Day 9'	System	16 Sep 2020 19:32:49

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T14:00:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '18fcb732-7baa-451a-90ba-a6cacb914081'	System	18 Sep 2020 21:00:19
User entered 'No (N)'	System	18 Sep 2020 21:00:19

FDA-CBER-2022-1614-0506088

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-18T14:00:18', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '18fcb732-7baa-451a-90ba-a6cacb914081'	System	18 Sep 2020 21:00:19
User entered '18 Sep 2020 14:00'	System	18 Sep 2020 21:00:19

FDA-CBER-2022-1614-0506089

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0506090

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:32:49

FDA-CBER-2022-1614-0506091

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Sep 2020 10:31:49
User entered 'Day 10'	System	18 Sep 2020 10:31:49

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e689955e-e3d1-472c-a312-97ebbfb8e423'	System	19 Sep 2020 19:08:53
User entered 'No (N)'	System	19 Sep 2020 19:08:53

FDA-CBER-2022-1614-0506093

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-19T12:08:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e689955e-e3d1-472c-a312-97ebbfb8e423'	System	19 Sep 2020 19:08:53
User entered '19 Sep 2020 12:08'	System	19 Sep 2020 19:08:53

FDA-CBER-2022-1614-0506094

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0506095

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 10:31:49

FDA-CBER-2022-1614-0506096

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	18 Sep 2020 21:00:11
User entered 'Day 11'	System	18 Sep 2020 21:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:03:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '272d98bb-4ffe-43ba-8fc6-ff22d7095f16'	System	20 Sep 2020 19:04:21
User entered 'No (N)'	System	20 Sep 2020 19:04:21

FDA-CBER-2022-1614-0506098

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-20T12:04:19', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '272d98bb-4ffe-43ba-8fc6-ff22d7095f16'	System	20 Sep 2020 19:04:21
User entered '20 Sep 2020 12:04'	System	20 Sep 2020 19:04:21

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0506100

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 21:00:11

FDA-CBER-2022-1614-0506101

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	19 Sep 2020 19:08:41
User entered 'Day 12'	System	19 Sep 2020 19:08:41

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T13:00:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e22c7304-c868-4d13-9da4-46f03e60c8ba'	System	21 Sep 2020 20:00:16
User entered 'No (N)'	System	21 Sep 2020 20:00:16

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-21T13:00:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e22c7304-c868-4d13-9da4-46f03e60c8ba'	System	21 Sep 2020 20:00:16
User entered '21 Sep 2020 13:00'	System	21 Sep 2020 20:00:16

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 19:08:41

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 19:08:41

FDA-CBER-2022-1614-0506106

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	20 Sep 2020 19:03:40
User entered 'Day 13'	System	20 Sep 2020 19:03:40

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:37:11', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '72924c0d-f4fa-4f6e-94be-98bd043b7797'	System	22 Sep 2020 23:37:21
User entered 'No (N)'	System	22 Sep 2020 23:37:21

FDA-CBER-2022-1614-0506108

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-22T16:37:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '72924c0d-f4fa-4f6e-94be-98bd043b7797'	System	22 Sep 2020 23:37:21
User entered '22 Sep 2020 16:37'	System	22 Sep 2020 23:37:21

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0506110

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 19:03:40

FDA-CBER-2022-1614-0506111

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	21 Sep 2020 20:00:11
User entered 'Day 14'	System	21 Sep 2020 20:00:11

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'be5eb078-1ce2-44cb-99dc-7d9a0a64d310'	System	23 Sep 2020 19:14:36
User entered 'No (N)'	System	23 Sep 2020 19:14:36

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-23T12:14:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'be5eb078-1ce2-44cb-99dc-7d9a0a64d310'	System	23 Sep 2020 19:14:36
User entered '23 Sep 2020 12:14'	System	23 Sep 2020 19:14:36

FDA-CBER-2022-1614-0506114

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0506115

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 20:00:11

FDA-CBER-2022-1614-0506116

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	22 Sep 2020 23:37:10
User entered 'Day 15'	System	22 Sep 2020 23:37:10

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:54:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '428bc41a-6919-4c23-8ec4-90a549d20108'	System	24 Sep 2020 20:54:09
User entered 'Yes (Y)'	System	24 Sep 2020 20:54:09

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-24T13:54:05', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '428bc41a-6919-4c23-8ec4-90a549d20108'	System	24 Sep 2020 20:54:09
User entered '24 Sep 2020 13:54'	System	24 Sep 2020 20:54:09

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 23:37:10

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 23:37:10

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	23 Sep 2020 19:14:26
User entered 'Day 16'	System	23 Sep 2020 19:14:26

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:43:06', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5653762e-340d-4c1b-a186-13df5afd8931'	System	25 Sep 2020 19:43:12
User entered 'No (N)'	System	25 Sep 2020 19:43:12

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-25T12:43:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5653762e-340d-4c1b-a186-13df5afd8931'	System	25 Sep 2020 19:43:12
User entered '25 Sep 2020 12:43'	System	25 Sep 2020 19:43:12

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 19:14:26

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 19:14:26

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	24 Sep 2020 20:53:56
User entered 'Day 17'	System	24 Sep 2020 20:53:56

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:14:12', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '22e8b570-7324-4c6a-92b6-aa58640eefbe'	System	26 Sep 2020 19:14:19
User entered 'No (N)'	System	26 Sep 2020 19:14:19

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-26T12:14:15', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '22e8b570-7324-4c6a-92b6-aa58640eefbe'	System	26 Sep 2020 19:14:19
User entered '26 Sep 2020 12:14'	System	26 Sep 2020 19:14:19

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 20:53:56

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 20:53:56

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	25 Sep 2020 19:43:05
User entered 'Day 18'	System	25 Sep 2020 19:43:05

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b1d5425c-ad7c-4f5b-aef0-957b2d21cab5'	System	27 Sep 2020 19:50:59
User entered 'No (N)'	System	27 Sep 2020 19:50:59

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-27T12:50:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'b1d5425c-ad7c-4f5b-aef0-957b2d21cab5'	System	27 Sep 2020 19:50:59
User entered '27 Sep 2020 12:50'	System	27 Sep 2020 19:50:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:43:05

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:43:05

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	26 Sep 2020 19:14:07
User entered 'Day 19'	System	26 Sep 2020 19:14:07

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:11:03', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fb97f896-5bf3-4070-bf7b-7151aa614599'	System	28 Sep 2020 20:11:11
User entered 'Yes (Y)'	System	28 Sep 2020 20:11:11

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-28T13:11:09', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fb97f896-5bf3-4070-bf7b-7151aa614599'	System	28 Sep 2020 20:11:11
User entered '28 Sep 2020 13:11'	System	28 Sep 2020 20:11:11

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:14:07

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:14:07

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	27 Sep 2020 19:50:52
User entered 'Day 20'	System	27 Sep 2020 19:50:52

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f31c7606-028b-4aa9-8f48-085b21ae1441'	System	29 Sep 2020 20:18:52
User entered 'Yes (Y)'	System	29 Sep 2020 20:18:52

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-29T13:18:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f31c7606-028b-4aa9-8f48-085b21ae1441'	System	29 Sep 2020 20:18:52
User entered '29 Sep 2020 13:18'	System	29 Sep 2020 20:18:52

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 19:50:52

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 19:50:52

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	28 Sep 2020 20:10:59
User entered 'Day 21'	System	28 Sep 2020 20:10:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '016997e8-2ffa-465b-ab7d-9ab52d2831fd'	System	30 Sep 2020 19:46:56
User entered 'No (N)'	System	30 Sep 2020 19:46:56

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-09-30T12:46:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '016997e8-2ffa-465b-ab7d-9ab52d2831fd'	System	30 Sep 2020 19:46:56
User entered '30 Sep 2020 12:46'	System	30 Sep 2020 19:46:56

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 20:10:59

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 20:10:59

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	29 Sep 2020 20:18:44
User entered 'Day 22'	System	29 Sep 2020 20:18:44

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '64eafede-959a-4027-826f-191a7f1bab75'	System	01 Oct 2020 19:09:54
User entered 'No (N)'	System	01 Oct 2020 19:09:54

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-01T12:09:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '64eafede-959a-4027-826f-191a7f1bab75'	System	01 Oct 2020 19:09:54
User entered '01 Oct 2020 12:09'	System	01 Oct 2020 19:09:54

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 20:18:44

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US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 20:18:44

FDA-CBER-2022-1614-0506156

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	30 Sep 2020 19:46:45
User entered 'Day 23'	System	30 Sep 2020 19:46:45

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ce0e8d4b-e6ed-4bf6-ac84-2f14521ae95e'	System	03 Oct 2020 16:38:50
User entered 'No (N)'	System	03 Oct 2020 16:38:50

FDA-CBER-2022-1614-0506158

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T09:38:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ce0e8d4b-e6ed-4bf6-ac84-2f14521ae95e'	System	03 Oct 2020 16:38:50
User entered '03 Oct 2020 09:38'	System	03 Oct 2020 16:38:50

FDA-CBER-2022-1614-0506159

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0506160

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:46:45

FDA-CBER-2022-1614-0506161

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	01 Oct 2020 19:09:37
User entered 'Day 24'	System	01 Oct 2020 19:09:37

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:59:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e7609568-363c-4fbf-8faf-447d645fcbb1'	System	03 Oct 2020 19:59:15
User entered 'No (N)'	System	03 Oct 2020 19:59:15

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-03T12:59:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'e7609568-363c-4fbf-8faf-447d645fcbb1'	System	03 Oct 2020 19:59:15
User entered '03 Oct 2020 12:59'	System	03 Oct 2020 19:59:15

FDA-CBER-2022-1614-0506164

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0506165

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(24)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 19:09:37

FDA-CBER-2022-1614-0506166

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	03 Oct 2020 16:38:39
User entered 'Day 25'	System	03 Oct 2020 16:38:39

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d1f61b5-196f-412b-882f-c91daaf5808f'	System	04 Oct 2020 19:08:18
User entered 'No (N)'	System	04 Oct 2020 19:08:18

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-04T12:08:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '3d1f61b5-196f-412b-882f-c91daaf5808f'	System	04 Oct 2020 19:08:18
User entered '04 Oct 2020 12:08'	System	04 Oct 2020 19:08:18

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0506170

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(25)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 16:38:39

FDA-CBER-2022-1614-0506171

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	03 Oct 2020 19:59:05
User entered 'Day 26'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0506172

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:28', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6b0d6a2a-195c-4b13-bce5-8c5ccc7a1aa1'	System	05 Oct 2020 19:04:34
User entered 'No (N)'	System	05 Oct 2020 19:04:34

FDA-CBER-2022-1614-0506173

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-05T12:04:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '6b0d6a2a-195c-4b13-bce5-8c5ccc7a1aa1'	System	05 Oct 2020 19:04:34
User entered '05 Oct 2020 12:04'	System	05 Oct 2020 19:04:34

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0506175

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(26)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 19:59:05

FDA-CBER-2022-1614-0506176

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	04 Oct 2020 19:08:12
User entered 'Day 27'	System	04 Oct 2020 19:08:12

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:11:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0e6680df-f123-46dc-9b95-bb00877c8231'	System	06 Oct 2020 19:11:08
User entered 'No (N)'	System	06 Oct 2020 19:11:08

FDA-CBER-2022-1614-0506178

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-06T12:11:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0e6680df-f123-46dc-9b95-bb00877c8231'	System	06 Oct 2020 19:11:08
User entered '06 Oct 2020 12:11'	System	06 Oct 2020 19:11:08

FDA-CBER-2022-1614-0506179

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0506180

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(27)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 19:08:12

FDA-CBER-2022-1614-0506181

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	05 Oct 2020 19:04:25
User entered 'Day 28'	System	05 Oct 2020 19:04:25

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5ef604e8-5f82-494e-a74f-d95c25bd5423'	System	07 Oct 2020 20:44:47
User entered 'Yes (Y)'	System	07 Oct 2020 20:44:47

FDA-CBER-2022-1614-0506183

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-07T13:44:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5ef604e8-5f82-494e-a74f-d95c25bd5423'	System	07 Oct 2020 20:44:47
User entered '07 Oct 2020 13:44'	System	07 Oct 2020 20:44:47

FDA-CBER-2022-1614-0506184

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0506185

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(28)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:04:25

FDA-CBER-2022-1614-0506186

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	06 Oct 2020 19:10:58
User entered 'Day 29'	System	06 Oct 2020 19:10:58

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '80bd20b1-f774-4742-9799-7cd6f89ab119'	System	08 Oct 2020 19:03:08
User entered 'No (N)'	System	08 Oct 2020 19:03:08

FDA-CBER-2022-1614-0506188

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-08T12:02:59', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '80bd20b1-f774-4742-9799-7cd6f89ab119'	System	08 Oct 2020 19:03:08
User entered '08 Oct 2020 12:02'	System	08 Oct 2020 19:03:08

FDA-CBER-2022-1614-0506189

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0506190

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(29)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:10:58

FDA-CBER-2022-1614-0506191

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	07 Oct 2020 20:44:39
User entered 'Day 30'	System	07 Oct 2020 20:44:39

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a21be886-0b7e-460e-843a-42bd4eca367a'	System	09 Oct 2020 19:25:36
User entered 'No (N)'	System	09 Oct 2020 19:25:36

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-09T12:25:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a21be886-0b7e-460e-843a-42bd4eca367a'	System	09 Oct 2020 19:25:36
User entered '09 Oct 2020 12:25'	System	09 Oct 2020 19:25:36

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0506195

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(30)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:44:39

FDA-CBER-2022-1614-0506196

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	08 Oct 2020 19:02:56
User entered 'Day 31'	System	08 Oct 2020 19:02:56

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bd146156-94e8-4f51-a22c-1765bffb5305'	System	10 Oct 2020 19:17:16
User entered 'No (N)'	System	10 Oct 2020 19:17:16

FDA-CBER-2022-1614-0506198

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bd146156-94e8-4f51-a22c-1765bffb5305'	System	10 Oct 2020 19:17:16
User entered '10 Oct 2020 12:17'	System	10 Oct 2020 19:17:16

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0506200

US3112173
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(31)
Generated On: 09 Jun 2021 15:16:38
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 19:02:56

FDA-CBER-2022-1614-0506201

US3112173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 21:30:54

US3112173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:15
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 21:30:54

US3112173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 21:30:54

US3112173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:15
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 21:30:54

US3112173
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 21:30:59

US3112173
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	17 Sep 2020 21:30:59

FDA-CBER-2022-1614-0506207

US3112173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:53
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:14:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated collection ' (Site from DM).	Natalie Moy (b) (4)	27 Oct 2020 20:46:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 8OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:53:19
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 23:02:55

US3112173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:53
User entered '24 Sep 2020'	Karen Mylerberg (b) (4)	24 Sep 2020 23:02:55

US3112173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:53
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	24 Sep 2020 23:02:55

US3112173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:53
User entered empty.	Karen Mylerberg (b) (4)	24 Sep 2020 23:02:55

FDA-CBER-2022-1614-0506211

US3112173
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:52:59
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	24 Sep 2020 23:03:03

US3112173
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	24 Sep 2020 23:03:03

US3112173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:53:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:13:23

US3112173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:53:43
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 21:13:23

US3112173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:53:43
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 21:13:23

FDA-CBER-2022-1614-0506216

US3112173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:53:43
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 21:13:23

US3112173
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:53:48
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:13:16

US3112173
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	26 Oct 2020 21:13:16

US3112173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:21

US3112173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:19
User entered '08 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:21

FDA-CBER-2022-1614-0506221

US3112173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:19
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:21

US3112173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'VISIT3'	System	26 Oct 2020 21:30:21

FDA-CBER-2022-1614-0506223

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '08 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506225

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '14:22'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506226

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '08 Oct 2020 14:22'	System	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506227

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '98.0' F	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506228

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506229

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered empty.	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '82'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506231

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506232

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '16'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506233

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506234

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '102'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506235

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506236

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:56:39
User entered '63'	Matthew Musikanth (b) (4)	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506237

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	26 Oct 2020 21:30:56

FDA-CBER-2022-1614-0506238

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37

FDA-CBER-2022-1614-0506239

US3112173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37

FDA-CBER-2022-1614-0506240

US3112173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
User closed query 'Source states PE was not done. Please update EDC' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 22:54:06
DataPoint Verified.	(b) (4), (b) (6)	15 Jan 2021 22:54:02
Query 'Source states PE was not done. Please update EDC' answered with 'has been updated ' (Site from CRA).	Brenda Grande (b) (4)	05 Jan 2021 23:37:16
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	05 Jan 2021 23:37:07
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	05 Jan 2021 23:36:54
DataPoint Un-verified.	Brenda Grande (b) (4)	05 Jan 2021 23:36:54
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Jan 2021 23:36:54
User opened query 'Source states PE was not done. Please update EDC' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 19:59:56
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:59:24
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:08

FDA-CBER-2022-1614-0506241

US3112173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	15 Jan 2021 22:54:02
DataPoint Un-verified.	Brenda Grande (b) (4)	05 Jan 2021 23:37:07
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4)	05 Jan 2021 23:37:07
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 19:59:24
User entered '08 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:08

US3112173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:01:03
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:24

US3112173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:01:03
User entered '08 Oct 2020'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:24

US3112173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:01:03
User entered '14:35'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:24

US3112173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '08 Oct 2020 14:35'	System	26 Oct 2020 21:31:24

FDA-CBER-2022-1614-0506246

US3112173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:19:10
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	26 Oct 2020 21:31:28

US3112173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	26 Oct 2020 21:31:28

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 64'	System	10 Aug 2020 21:08:50

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:31', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee3a47b1-d789-4fc4-94f8-6159a06db5fa'	System	10 Oct 2020 19:17:48
User entered 'No (N)'	System	10 Oct 2020 19:17:48

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:39', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee3a47b1-d789-4fc4-94f8-6159a06db5fa'	System	10 Oct 2020 19:17:48
User entered 'No (N)'	System	10 Oct 2020 19:17:48

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-10T12:17:44', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee3a47b1-d789-4fc4-94f8-6159a06db5fa'	System	10 Oct 2020 19:17:48
User entered '10 Oct 2020 12:17:44'	System	10 Oct 2020 19:17:48

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 71'	System	10 Aug 2020 21:08:50

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-19T11:01:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a596c911-09fa-4632-b127-0010fb1b3a00'	System	19 Oct 2020 18:04:16
User entered 'No (N)'	System	19 Oct 2020 18:04:16

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-19T11:01:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a596c911-09fa-4632-b127-0010fb1b3a00'	System	19 Oct 2020 18:04:16
User entered 'No (N)'	System	19 Oct 2020 18:04:16

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-19T11:01:33', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'a596c911-09fa-4632-b127-0010fb1b3a00'	System	19 Oct 2020 18:04:16
User entered '19 Oct 2020 11:01:33'	System	19 Oct 2020 18:04:16

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 78'	System	10 Aug 2020 21:08:50

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-24T11:09:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '26a39145-40a5-42a9-89fc-ce9a3c899b6a'	System	24 Oct 2020 18:09:23
User entered 'No (N)'	System	24 Oct 2020 18:09:23

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-24T11:09:13', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '26a39145-40a5-42a9-89fc-ce9a3c899b6a'	System	24 Oct 2020 18:09:23
User entered 'No (N)'	System	24 Oct 2020 18:09:23

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-10-24T11:09:20', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '26a39145-40a5-42a9-89fc-ce9a3c899b6a'	System	24 Oct 2020 18:09:23
User entered '24 Oct 2020 11:09:20'	System	24 Oct 2020 18:09:23

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 92'	System	10 Aug 2020 21:08:50

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-07T00:47:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b921768-5779-4315-a564-7aad83430d91'	System	07 Nov 2020 08:48:19
User entered 'No (N)'	System	07 Nov 2020 08:48:19

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-07T00:48:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b921768-5779-4315-a564-7aad83430d91'	System	07 Nov 2020 08:48:19
User entered 'No (N)'	System	07 Nov 2020 08:48:19

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-07T00:48:17', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '5b921768-5779-4315-a564-7aad83430d91'	System	07 Nov 2020 08:48:19
User entered '07 Nov 2020 00:48:17'	System	07 Nov 2020 08:48:19

FDA-CBER-2022-1614-0506270

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered 'Day 99'	System	10 Aug 2020 21:08:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-14T11:18:10', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bdd37fa1-56a1-4868-822c-6712c9e0e5db'	System	14 Nov 2020 19:18:37
User entered 'No (N)'	System	14 Nov 2020 19:18:37

US3112173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-14T11:18:25', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bdd37fa1-56a1-4868-822c-6712c9e0e5db'	System	14 Nov 2020 19:18:37
User entered 'No (N)'	System	14 Nov 2020 19:18:37

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-14T11:18:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bdd37fa1-56a1-4868-822c-6712c9e0e5db'	System	14 Nov 2020 19:18:37
User entered '14 Nov 2020 11:18:34'	System	14 Nov 2020 19:18:37

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 21:08:50

US3112173
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:55:04
Data entry locked.	System	10 Aug 2020 21:08:50
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 21:08:50

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-21T01:05:24', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bcf1b25e-198f-4218-8239-f67b2c68e221'	System	21 Nov 2020 09:05:50
User entered 'No (N)'	System	21 Nov 2020 09:05:50

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-21T01:05:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bcf1b25e-198f-4218-8239-f67b2c68e221'	System	21 Nov 2020 09:05:50
User entered 'No (N)'	System	21 Nov 2020 09:05:50

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-21T01:05:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'bcf1b25e-198f-4218-8239-f67b2c68e221'	System	21 Nov 2020 09:05:50
User entered '21 Nov 2020 01:05:48'	System	21 Nov 2020 09:05:50

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-25T10:10:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '88a2222d-643a-445b-aebf-ce564ff34dec'	System	25 Nov 2020 18:11:22
User entered 'No (N)'	System	25 Nov 2020 18:11:22

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-25T10:11:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '88a2222d-643a-445b-aebf-ce564ff34dec'	System	25 Nov 2020 18:11:22
User entered 'No (N)'	System	25 Nov 2020 18:11:22

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-11-25T10:11:16', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '88a2222d-643a-445b-aebf-ce564ff34dec'	System	25 Nov 2020 18:11:22
User entered '25 Nov 2020 10:11:16'	System	25 Nov 2020 18:11:22

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:11:18

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US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-02T09:50:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5f1e49-5c67-4fd6-bfd1-63990506eaec'	System	02 Dec 2020 17:51:07
User entered 'No (N)'	System	02 Dec 2020 17:51:07

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-02T09:50:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5f1e49-5c67-4fd6-bfd1-63990506eaec'	System	02 Dec 2020 17:51:07
User entered 'No (N)'	System	02 Dec 2020 17:51:07

US3112173
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-02T09:51:02', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '8d5f1e49-5c67-4fd6-bfd1-63990506eaec'	System	02 Dec 2020 17:51:07
User entered '02 Dec 2020 09:51:02'	System	02 Dec 2020 17:51:07

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-11T12:40:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '08716cc2-9b3b-426b-93ae-af56d2d03686'	System	11 Dec 2020 20:41:04
User entered 'No (N)'	System	11 Dec 2020 20:41:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-11T12:40:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '08716cc2-9b3b-426b-93ae-af56d2d03686'	System	11 Dec 2020 20:41:04
User entered 'No (N)'	System	11 Dec 2020 20:41:04

US3112173
Folder: New Safety Follow Up Diary (1)
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Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-11T12:40:57', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '08716cc2-9b3b-426b-93ae-af56d2d03686'	System	11 Dec 2020 20:41:04
User entered '11 Dec 2020 12:40:57'	System	11 Dec 2020 20:41:04

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-16T00:01:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2b72cc6b-b601-464d-abcd-d833ed66cf75'	System	16 Dec 2020 08:01:50
User entered 'No (N)'	System	16 Dec 2020 08:01:50

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-16T00:01:40', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2b72cc6b-b601-464d-abcd-d833ed66cf75'	System	16 Dec 2020 08:01:50
User entered 'No (N)'	System	16 Dec 2020 08:01:50

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-16T00:01:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2b72cc6b-b601-464d-abcd-d833ed66cf75'	System	16 Dec 2020 08:01:50
User entered '16 Dec 2020 00:01:48'	System	16 Dec 2020 08:01:50

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-25T12:04:26', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0508040c-9e66-4afb-91ce-0fea372ef93a'	System	25 Dec 2020 20:04:41
User entered 'No (N)'	System	25 Dec 2020 20:04:41

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-25T12:04:30', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0508040c-9e66-4afb-91ce-0fea372ef93a'	System	25 Dec 2020 20:04:41
User entered 'No (N)'	System	25 Dec 2020 20:04:41

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-25T12:04:38', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '0508040c-9e66-4afb-91ce-0fea372ef93a'	System	25 Dec 2020 20:04:41
User entered '25 Dec 2020 12:04:38'	System	25 Dec 2020 20:04:41

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-30T00:01:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cdb11f31-fba6-4be0-aa0e-419a9302d200'	System	30 Dec 2020 08:02:04
User entered 'No (N)'	System	30 Dec 2020 08:02:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-30T00:01:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cdb11f31-fba6-4be0-aa0e-419a9302d200'	System	30 Dec 2020 08:02:04
User entered 'No (N)'	System	30 Dec 2020 08:02:04

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2020-12-30T00:02:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cdb11f31-fba6-4be0-aa0e-419a9302d200'	System	30 Dec 2020 08:02:04
User entered '30 Dec 2020 00:02:00'	System	30 Dec 2020 08:02:04

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-06T00:21:36', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '038b5e41-a2ec-451b-95b6-a222108c41dd'	System	06 Jan 2021 08:21:49
User entered 'No (N)'	System	06 Jan 2021 08:21:49

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-06T00:21:42', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '038b5e41-a2ec-451b-95b6-a222108c41dd'	System	06 Jan 2021 08:21:49
User entered 'No (N)'	System	06 Jan 2021 08:21:49

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-06T00:21:47', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '038b5e41-a2ec-451b-95b6-a222108c41dd'	System	06 Jan 2021 08:21:49
User entered '06 Jan 2021 00:21:47'	System	06 Jan 2021 08:21:49

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-13T00:01:45', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2959ad3f-b1bf-47d7-8ed6-f5a29c204084'	System	13 Jan 2021 08:01:56
User entered 'No (N)'	System	13 Jan 2021 08:01:56

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-13T00:01:48', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2959ad3f-b1bf-47d7-8ed6-f5a29c204084'	System	13 Jan 2021 08:01:56
User entered 'No (N)'	System	13 Jan 2021 08:01:56

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-13T00:01:53', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2959ad3f-b1bf-47d7-8ed6-f5a29c204084'	System	13 Jan 2021 08:01:56
User entered '13 Jan 2021 00:01:53'	System	13 Jan 2021 08:01:56

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-20T10:15:46', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f33381c4-2d02-4769-9442-19e656c11770'	System	20 Jan 2021 18:16:02
User entered 'No (N)'	System	20 Jan 2021 18:16:02

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-20T10:15:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f33381c4-2d02-4769-9442-19e656c11770'	System	20 Jan 2021 18:16:02
User entered 'No (N)'	System	20 Jan 2021 18:16:02

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-20T10:15:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'f33381c4-2d02-4769-9442-19e656c11770'	System	20 Jan 2021 18:16:02
User entered '20 Jan 2021 10:15:58'	System	20 Jan 2021 18:16:02

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-27T00:02:04', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd5e5fcbe-8f70-47e7-904a-0a312a1cd427'	System	27 Jan 2021 08:02:16
User entered 'No (N)'	System	27 Jan 2021 08:02:16

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-27T00:02:07', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd5e5fcbe-8f70-47e7-904a-0a312a1cd427'	System	27 Jan 2021 08:02:16
User entered 'No (N)'	System	27 Jan 2021 08:02:16

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-01-27T00:02:14', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'd5e5fcbe-8f70-47e7-904a-0a312a1cd427'	System	27 Jan 2021 08:02:16
User entered '27 Jan 2021 00:02:14'	System	27 Jan 2021 08:02:16

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-03T00:01:51', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58c176f5-af17-455f-8364-1f534d1e05cb'	System	03 Feb 2021 08:02:01
User entered 'No (N)'	System	03 Feb 2021 08:02:01

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-03T00:01:54', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58c176f5-af17-455f-8364-1f534d1e05cb'	System	03 Feb 2021 08:02:01
User entered 'No (N)'	System	03 Feb 2021 08:02:01

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-03T00:01:58', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58c176f5-af17-455f-8364-1f534d1e05cb'	System	03 Feb 2021 08:02:01
User entered '03 Feb 2021 00:01:58'	System	03 Feb 2021 08:02:01

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-12T19:07:49', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c3767b93-8174-48c4-ba0d-73987f629161'	System	13 Feb 2021 03:09:12
User entered 'No (N)'	System	13 Feb 2021 03:09:12

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-12T19:07:52', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c3767b93-8174-48c4-ba0d-73987f629161'	System	13 Feb 2021 03:09:12
User entered 'No (N)'	System	13 Feb 2021 03:09:12

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-12T19:07:56', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'c3767b93-8174-48c4-ba0d-73987f629161'	System	13 Feb 2021 03:09:12
User entered '12 Feb 2021 19:07:56'	System	13 Feb 2021 03:09:12

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-17T16:31:27', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58d88395-dc17-4026-a587-3a5e7d37240d'	System	18 Feb 2021 00:31:39
User entered 'No (N)'	System	18 Feb 2021 00:31:39

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-17T16:31:32', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58d88395-dc17-4026-a587-3a5e7d37240d'	System	18 Feb 2021 00:31:39
User entered 'No (N)'	System	18 Feb 2021 00:31:39

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-17T16:31:34', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '58d88395-dc17-4026-a587-3a5e7d37240d'	System	18 Feb 2021 00:31:39
User entered '17 Feb 2021 16:31:34'	System	18 Feb 2021 00:31:39

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:02:31-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered 'Yes (Y)'	System	24 Feb 2021 08:03:42

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:02:40-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered 'No (N)'	System	24 Feb 2021 08:03:42

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:02:50-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered 'No (N)'	System	24 Feb 2021 08:03:42

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:02:57-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered 'Yes (Y)'	System	24 Feb 2021 08:03:42

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:03:15-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Feb 2021 08:03:42

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-02-24T00:03:31-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '30018312-45d9-423b-a5e2-f10587b230e1'	System	24 Feb 2021 08:03:42
User entered '24 Feb 2021 08:03:31'	System	24 Feb 2021 08:03:42

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-03T00:03:45-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a6d92cf-d778-49f6-bad8-d0594b3e9a71'	System	03 Mar 2021 08:03:59
User entered 'No (N)'	System	03 Mar 2021 08:03:59

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-03T00:03:49-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a6d92cf-d778-49f6-bad8-d0594b3e9a71'	System	03 Mar 2021 08:03:59
User entered 'No (N)'	System	03 Mar 2021 08:03:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-03T00:03:55-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '2a6d92cf-d778-49f6-bad8-d0594b3e9a71'	System	03 Mar 2021 08:03:59
User entered '03 Mar 2021 00:03:55'	System	03 Mar 2021 08:03:59

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-10T10:18:12-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbd94571-dd29-4d45-9871-6c69dcba036f'	System	10 Mar 2021 18:18:52
User entered 'No (N)'	System	10 Mar 2021 18:18:52

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-10T10:18:17-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbd94571-dd29-4d45-9871-6c69dcba036f'	System	10 Mar 2021 18:18:52
User entered 'No (N)'	System	10 Mar 2021 18:18:52

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-10T10:18:21-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'cbd94571-dd29-4d45-9871-6c69dcba036f'	System	10 Mar 2021 18:18:52
User entered '10 Mar 2021 10:18:21'	System	10 Mar 2021 18:18:52

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-17T09:53:16-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '23c0931f-351c-4f22-831a-c21f05a68295'	System	17 Mar 2021 16:53:28
User entered 'No (N)'	System	17 Mar 2021 16:53:28

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-17T09:53:20-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '23c0931f-351c-4f22-831a-c21f05a68295'	System	17 Mar 2021 16:53:28
User entered 'No (N)'	System	17 Mar 2021 16:53:28

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-17T09:53:22-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '23c0931f-351c-4f22-831a-c21f05a68295'	System	17 Mar 2021 16:53:28
User entered '17 Mar 2021 09:53:22'	System	17 Mar 2021 16:53:28

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-24T08:12:07-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fbc9d560-97c4-4f33-a17a-66e90b5402de'	System	24 Mar 2021 15:12:26
User entered 'No (N)'	System	24 Mar 2021 15:12:26

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-24T08:12:14-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fbc9d560-97c4-4f33-a17a-66e90b5402de'	System	24 Mar 2021 15:12:26
User entered 'No (N)'	System	24 Mar 2021 15:12:26

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-24T08:12:21-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'fbc9d560-97c4-4f33-a17a-66e90b5402de'	System	24 Mar 2021 15:12:26
User entered '24 Mar 2021 08:12:21'	System	24 Mar 2021 15:12:26

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-31T08:40:46-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '681b0de0-f262-473d-899b-41b3c8e789cb'	System	31 Mar 2021 15:40:58
User entered 'No (N)'	System	31 Mar 2021 15:40:58

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-31T08:40:51-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '681b0de0-f262-473d-899b-41b3c8e789cb'	System	31 Mar 2021 15:40:58
User entered 'No (N)'	System	31 Mar 2021 15:40:58

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-31T08:40:55-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '681b0de0-f262-473d-899b-41b3c8e789cb'	System	31 Mar 2021 15:40:58
User entered '31 Mar 2021 08:40:55'	System	31 Mar 2021 15:40:58

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-07T08:44:33-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee21e6f8-045c-465f-99b1-77220c80cce4'	System	07 Apr 2021 15:44:47
User entered 'No (N)'	System	07 Apr 2021 15:44:47

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-07T08:44:38-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee21e6f8-045c-465f-99b1-77220c80cce4'	System	07 Apr 2021 15:44:47
User entered 'No (N)'	System	07 Apr 2021 15:44:47

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-07T08:44:42-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ee21e6f8-045c-465f-99b1-77220c80cce4'	System	07 Apr 2021 15:44:47
User entered '07 Apr 2021 08:44:42'	System	07 Apr 2021 15:44:47

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-15T11:05:10-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '9164f0c4-738b-48cb-87c3-b8c95593f6b3'	System	15 Apr 2021 18:33:02
User entered 'No (N)'	System	15 Apr 2021 18:33:02

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-15T11:05:14-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '9164f0c4-738b-48cb-87c3-b8c95593f6b3'	System	15 Apr 2021 18:33:02
User entered 'No (N)'	System	15 Apr 2021 18:33:02

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-15T11:05:17-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '9164f0c4-738b-48cb-87c3-b8c95593f6b3'	System	15 Apr 2021 18:33:02
User entered '15 Apr 2021 11:05:17'	System	15 Apr 2021 18:33:02

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:01-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered 'Yes (Y)'	System	21 Apr 2021 20:18:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:18-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered 'No (N)'	System	21 Apr 2021 20:18:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:22-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered 'No (N)'	System	21 Apr 2021 20:18:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:32-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered 'Yes (Y)'	System	21 Apr 2021 20:18:04

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:42-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Apr 2021 20:18:04

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-21T13:17:54-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: 'ff83785f-98d0-4a1e-878c-fe9481f911d2'	System	21 Apr 2021 20:18:04
User entered '21 Apr 2021 13:17:54'	System	21 Apr 2021 20:18:04

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:11:18

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-29T10:57:54-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '1aa4a615-8cb7-4430-97ae-1657db46133c'	System	29 Apr 2021 17:58:11
User entered 'No (N)'	System	29 Apr 2021 17:58:11

US3112173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:16:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-29T10:57:58-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '1aa4a615-8cb7-4430-97ae-1657db46133c'	System	29 Apr 2021 17:58:11
User entered 'No (N)'	System	29 Apr 2021 17:58:11

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-04-29T10:58:04-07:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '1aa4a615-8cb7-4430-97ae-1657db46133c'	System	29 Apr 2021 17:58:11
User entered '29 Apr 2021 10:58:04'	System	29 Apr 2021 17:58:11

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:11:18

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US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:11:18

US3112173
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:16:38
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:18
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:11:18

US3112173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:16:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-03T00:04:05-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '340fd1ec-3609-4ee4-a18a-0686fa2b0e43'	System	03 Mar 2021 08:04:13
User entered 'No (N)'	System	03 Mar 2021 08:04:13

US3112173
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 15:16:38
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:12:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A14AE536-0E55-46A8-BFE2-249B6DE7E31C)', Time: '2021-03-03T00:04:11-08:00', User OID: 'PatientReportedOutcome (US3112173)', ODM File OID: '340fd1ec-3609-4ee4-a18a-0686fa2b0e43'	System	03 Mar 2021 08:04:13
User entered '03 Mar 2021 00:04:11'	System	03 Mar 2021 08:04:13

US3112173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:00
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	16 Nov 2020 18:25:00

US3112173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:00
User entered '6 Nov 2020'	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:25:00

US3112173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:00
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4)	16 Nov 2020 18:25:00

FDA-CBER-2022-1614-0506661

US3112173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:00
User entered empty.	Nicolle Mendez (b) (4)	16 Nov 2020 18:25:00

US3112173
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:48:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:03
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:25:05

US3112173
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	16 Nov 2020 18:25:05

US3112173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:29
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Dec 2020 00:35:11

US3112173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:29
User entered '09 Dec 2020'	Matthew Musikanth (b) (4)	10 Dec 2020 00:35:11

US3112173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:29
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	10 Dec 2020 00:35:11

US3112173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:29
User entered empty.	Matthew Musikanth (b) (4)	10 Dec 2020 00:35:11

FDA-CBER-2022-1614-0506668

US3112173
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:43:33
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	10 Dec 2020 00:35:02

US3112173
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	10 Dec 2020 00:35:02

US3112173
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:39
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:23:45

US3112173
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:39
User entered '8 Jan 2021'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:23:45

US3112173
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:39
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:23:45

US3112173
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:39
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:23:45

FDA-CBER-2022-1614-0506674

US3112173
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:58
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:23:30

US3112173
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	08 Jan 2021 21:23:30

US3112173
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:42
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:28

US3112173
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:42
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:28

US3112173
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:42
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:28

US3112173
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:42
User entered empty.	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:28

US3112173
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:46
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:32

US3112173
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	09 Feb 2021 19:52:32

US3112173
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 9Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:18:58
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 9Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 16:00:21
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:38:48
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 9Mar2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D57 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:03:45
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:38:49

US3112173
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:38:48
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:38:49

US3112173
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:38:48
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:38:49

US3112173
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'VISIT4'	System	09 Mar 2021 22:38:49

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US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '11:54'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '9 Mar 2021 11:54'	System	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506690

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '97.9' F	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered empty.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '81'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'bpm'	System	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506695

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '13'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'breaths/min'	System	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506697

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '109'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506698

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506699

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:49:20
User entered '62'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:57

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered 'mmHg'	System	30 Mar 2021 15:57:57

FDA-CBER-2022-1614-0506701

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37

FDA-CBER-2022-1614-0506702

US3112173
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37

FDA-CBER-2022-1614-0506703

US3112173
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 9MAR2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:18:45
Query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 9MAR2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:59:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:38:58
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 9MAR2021. However, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:37:37
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:13

FDA-CBER-2022-1614-0506704

US3112173
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:38:58
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:13

US3112173
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:39:05
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:25

US3112173
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:39:05
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:25

US3112173
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:39:05
User entered '12:05'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:25

US3112173
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '9 Mar 2021 12:05'	System	09 Mar 2021 22:39:25

FDA-CBER-2022-1614-0506709

US3112173
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:22
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:39:13
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:28

US3112173
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:23:37
User entered '1'	System	09 Mar 2021 22:39:28

US3112173
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:36:26

US3112173
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:26
User entered '08 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 20:36:26

US3112173
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Apr 2021 20:36:26

US3112173
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:26
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:36:26

US3112173
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	08 Apr 2021 22:53:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:36:30

US3112173
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 20:36:30

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:47:48
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:49:56

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:47:48
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:49:56

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:47:48
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:49:56

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 22:49:56

FDA-CBER-2022-1614-0506721

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:42:59
User closed query 'Data field is actually for date subject signed consent. Please update.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 18:42:57
Query 'Data field is actually for date subject signed consent. Please update.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:57:08
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:56:56
User entered '5 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:56:56
User opened query 'Data field is actually for date subject signed consent. Please update.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:39:55
DataPoint Verified.	(b) (4), (b) (6)	06 Mar 2021 01:41:19
User closed query 'Please clarify. Source has ICF version 24Dec2020 signed by subject on 05Jan2021 filed in chart. Please update as necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Mar 2021 01:41:14
Query 'Please clarify. Source has ICF version 24Dec2020 signed by subject on 05Jan2021 filed in chart. Please update as necessary.' answered with 'updated, thank you' (Site from CRA).	Natalie Moy (b) (4) (b) (4)	02 Mar 2021 23:33:25
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	02 Mar 2021 23:33:16
User entered '24 Dec 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	02 Mar 2021 23:33:16
User opened query 'Please clarify. Source has ICF version 24Dec2020 signed by subject on 05Jan2021 filed in chart. Please update as necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 22:49:58
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

FDA-CBER-2022-1614-0506722

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:42:59
User entered '0'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:56:56
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:08:31

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 18:42:59
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:56:56
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:08:31

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:53:07
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:53:07
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:48:58
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	05 Jan 2021 22:50:07

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:16:38
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	05 Jan 2021 22:50:07

FDA-CBER-2022-1614-0506732

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered empty.	System	05 Jan 2021 22:51:09
DataPoint set to visible.	System	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered empty.	System	05 Jan 2021 22:51:09
DataPoint set to visible.	System	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '13:37'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '5 Jan 2021 13:37'	System	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '98' F	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '85'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'bpm'	System	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	06 Mar 2021 01:45:42
User closed query 'Please clarify. Source indicates RR=16. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Mar 2021 01:45:40
Query 'Please clarify. Source indicates RR=16. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	05 Mar 2021 15:46:20
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	05 Mar 2021 15:46:15
User entered '16' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Mar 2021 15:46:15
User opened query 'Please clarify. Source indicates RR=16. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 22:52:33
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '13'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'breaths/min'	System	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '116'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '83'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	05 Jan 2021 22:51:09

FDA-CBER-2022-1614-0506754

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:16:38
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered empty.	System	05 Jan 2021 22:51:09
DataPoint set to visible.	System	05 Jan 2021 22:50:07

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '14:31'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '5 Jan 2021 14:31'	System	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '98.3' F	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '72'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'bpm'	System	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '16'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'breaths/min'	System	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '114'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	05 Jan 2021 22:51:09

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:51:46
User entered '78'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:09

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	05 Jan 2021 22:51:09

FDA-CBER-2022-1614-0506773

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:17
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:20

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:17
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:20

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:16:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mRNA-1273'	System	05 Jan 2021 22:51:36
DataPoint set to visible.	System	05 Jan 2021 22:50:07

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered '14:00'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '5 Jan 2021 14:00'	System	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:34
User entered 'ONCE'	System	05 Jan 2021 22:51:36

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 22:51:36

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:50
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:47

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:50
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:47

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:50
User entered '13:46'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:47

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '5 Jan 2021 13:46'	System	05 Jan 2021 22:51:47

FDA-CBER-2022-1614-0506789

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:57
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:59

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:57
User entered '5 Jan 2021'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:59

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:57
User entered '13:42'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:51:59

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:16:38
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '5 Jan 2021 13:42'	System	05 Jan 2021 22:51:59

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US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:03
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Jan 2021 22:52:02

US3112173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	05 Jan 2021 22:52:02

US3112173
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:42
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	12 Jan 2021 23:04:55

US3112173
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:42
User entered '12 Jan 2021'	Karen Mylerberg (b) (4) (b) (4)	12 Jan 2021 23:04:55

US3112173
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:42
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	12 Jan 2021 23:04:55

US3112173
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:42
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	12 Jan 2021 23:04:55

US3112173
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	12 Jan 2021 23:04:46

US3112173
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	12 Jan 2021 23:04:46

US3112173
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	12 Jan 2021 23:04:46
DataPoint set to visible.	System	12 Jan 2021 23:04:46

US3112173
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:59:38
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:15:48

US3112173
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:59:38
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:15:48

US3112173
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:59:38
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:15:48

US3112173
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'OLD29'	System	02 Feb 2021 22:15:48

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US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

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US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '13:09'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '2 Feb 2021 13:09'	System	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '98' F	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered empty.	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '82'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'bpm'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506816

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '16'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'breaths/min'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506818

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '130'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506820

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '71'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506822

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506823

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '13:55'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '2 Feb 2021 13:55'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506827

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Feb 2021 22:18:03
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Feb 2021 22:18:03
User entered '98.2' F reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:18:03
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Feb 2021 22:17:52
User entered '982' F reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:52
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Feb 2021 22:16:52
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Feb 2021 22:16:52
User entered '98.2' F reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:52
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Feb 2021 22:16:44
User entered '982' F	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered empty.	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '76'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'bpm'	System	02 Feb 2021 22:16:44

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US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '16'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'breaths/min'	System	02 Feb 2021 22:16:44

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US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '128'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	02 Feb 2021 22:16:44

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US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:22
User entered '74'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:16:44

US3112173
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	02 Feb 2021 22:16:44

FDA-CBER-2022-1614-0506838

US3112173
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:30
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:01

US3112173
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:30
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:01

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mRNA-1273'	System	02 Feb 2021 22:17:32
DataPoint set to visible.	System	12 Jan 2021 23:04:46

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered '13:24'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '2 Feb 2021 13:24'	System	02 Feb 2021 22:17:32

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US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:00:53
User entered 'ONCE'	System	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:16:38
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 22:17:32

US3112173
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:01:00
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	02 Feb 2021 22:17:38

US3112173
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	02 Feb 2021 22:17:38

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US3112173
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:13
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:01

US3112173
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:13
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:01

US3112173
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:13
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:01

US3112173
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:16:38
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:13
User entered empty.	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:01

US3112173
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:04:18
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 19:52:04

US3112173
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:16:38
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '1'	System	09 Feb 2021 19:52:04

FDA-CBER-2022-1614-0506858

US3112173
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:29
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:47

US3112173
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:29
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:47

US3112173
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:29
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:39:47

US3112173
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:16:38
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'OLD57'	System	09 Mar 2021 22:39:47

FDA-CBER-2022-1614-0506862

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '11:54'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '9 Mar 2021 11:54'	System	09 Mar 2021 22:40:28

FDA-CBER-2022-1614-0506866

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '97.9' F	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '81'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'bpm'	System	09 Mar 2021 22:40:28

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US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '13'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'breaths/min'	System	09 Mar 2021 22:40:28

FDA-CBER-2022-1614-0506873

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '109'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	09 Mar 2021 22:40:28

FDA-CBER-2022-1614-0506875

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:34:55
User entered '62'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:40:28

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered 'mmHg'	System	09 Mar 2021 22:40:28

FDA-CBER-2022-1614-0506877

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51

FDA-CBER-2022-1614-0506878

US3112173
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:16:38
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51

FDA-CBER-2022-1614-0506879

US3112173
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:48:00
User closed query 'Please clarify. Source indicates No PE completed. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 23:47:57
Query 'Please clarify. Source indicates No PE completed. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:55:44
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:55:29
User opened query 'Please clarify. Source indicates No PE completed. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:37:03
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:10

US3112173
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:16:38
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 23:48:00
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 15:55:29
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:10

US3112173
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:37:32
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:23

US3112173
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:37:32
User entered '9 Mar 2021'	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:23

US3112173
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:37:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Mar 2021 22:53:29
User entered '12:05' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Mar 2021 22:53:23
User entered '12:5' (non-conformant).	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 22:53:23

US3112173
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:16:38
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:07:51
User entered '9 Mar 2021 12:05'	System	09 Mar 2021 22:53:29
User entered '9 Mar 2021 12:5' (non-conformant).	System	09 Mar 2021 22:53:23

US3112173
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:16:38
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:55
User closed query 'Per DM CLR: Medical Attention was checked for DAY 15-16 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:38:41
Query 'Per DM CLR: Medical Attention was checked for DAY 15-16 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' answered with 'Please note that eDiary survey question is posited as follows "Did you receive ANY medical attention (doctor visit, other) for ANY illness or symptoms?" Patient reported receipt of medical attention pertaining to other already reported adverse event unrelated to vaccine or study procedures. Please see MAAE term; "Pain secondary to Spinal Fusion" and concomitant procedure "Spinal Fusion"' (Site from DM).	Matthew Musikanth (b) (4)	20 Apr 2021 20:18:27

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US3112173
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:16:38
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Medical Attention was checked for DAY 15-16 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:37:24
Query 'Per DM CLR: Medical Attention was checked for DAY 8-16 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' canceled (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:37:20
User opened query 'Per DM CLR: Medical Attention was checked for DAY 8-16 on Diary Dose 1. However, there is no Solicited Adverse Reaction that lasted beyond 7 days that is recorded in the AE eCRF. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please review and verify if there is a Solicited Adverse Reaction that should be captured in the AE eCRF. Otherwise, clarify what is the reason for seeking Medical Attention. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:29:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13

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US3112173
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:16:38
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:59:55
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:34:11

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:23:54
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 06:23:54
Data point term sent to Coder	System	19 Nov 2020 00:35:48
User entered 'Pain secondary to Spinal Fusion'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 23:42:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:40:00
User entered '24 Aug 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:40:00
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	19 Nov 2020 00:35:15
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	19 Nov 2020 00:35:15
User entered '25 Aug 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:15
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	19 Nov 2020 00:35:03
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	19 Nov 2020 00:35:03
User entered '25 Apr 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

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US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

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US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '21 Sep 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Severity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #23 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 15:34:58
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #23 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	08 Jan 2021 21:40:18
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #23 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:37:52
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '1'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

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US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:16:38
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:35:03

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Healing abnormal NEC, PT: Impaired healing, LLT: Wound healing delayed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:25:57
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 06:25:57
Data point term sent to Coder	System	19 Nov 2020 00:36:49
User entered 'Poor wound healing'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'No (N)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '17 Sep 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

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US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

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US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 00:36:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 00:36:10
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 00:36:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '03 Oct 2020'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

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US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Severity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 00:36:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 00:36:10
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 00:36:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

FDA-CBER-2022-1614-0506939

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

FDA-CBER-2022-1614-0506940

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '1'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered '0'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:02
User entered empty.	Matthew Musikanth (b) (4)	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 00:36:10

US3112173
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:16:38
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:36:02

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Joint dislocation, LLT: Dislocated hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:08:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:08:06
Data point term sent to Coder	System	24 Feb 2021 23:07:16
User entered 'dislocated left hip'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '18 Feb 2021'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '18 Feb 2021'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Severity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Not Related (NOT RELATED)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Not Applicable (NOT APPLICABLE)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '0'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 04:59:15
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'awaiting medical records to confirm medication ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	15 Mar 2021 18:28:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:27:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '1'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

FDA-CBER-2022-1614-0506984

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered '1'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:23:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:55
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:16:38
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 23:06:57

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
AEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:31
User entered 'USA-US062-2021-mRNA-1273-P301000017'	System	26 Apr 2021 18:21:39
User entered 'New'	(b) (4), (b) (6)	26 Apr 2021 18:21:39

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Adverse event

Audit	User	Time (GMT)
User opened query 'For coding purposes, REVISION OF LEFT HIP REPLACEMENT is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	29 Apr 2021 12:17:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Revision of hip arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 19:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
Data point term sent to Coder	System	23 Apr 2021 16:59:01
User closed query 'DM-Coding: It is a medical and surgical procedure and not appropriate as an adverse event. Please enter/add the diagnosis for which this procedure was performed and amend /update the term accordingly.' (Site from System).	System	23 Apr 2021 16:58:38
Query 'DM-Coding: It is a medical and surgical procedure and not appropriate as an adverse event. Please enter/add the diagnosis for which this procedure was performed and amend /update the term accordingly.' answered with 'Left hip needed a revision to avoid future dislocations, no ongoing AE, reported as term since patient spent a night in the hospital for procedure. project manager directed to reports as SAE. ' (Site from System).	Matthew Musikanth (b) (4)	23 Apr 2021 16:58:38
User opened query 'DM-Coding: It is a medical and surgical procedure and not appropriate as an adverse event. Please enter/add the diagnosis for which this procedure was performed and amend /update the term accordingly.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:40:46
Data point term sent to Coder	System	23 Apr 2021 16:36:15
User entered 'Revision of left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

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US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Severity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '20 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '1'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Narrative

Audit	User	Time (GMT)
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)	03 May 2021 20:18:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 20:18:46
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:35:31

US3112173
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:16:38
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:35:31

US3112173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:16:38

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:33:03
User closed query 'Per CDM: Per Diary Dose 1 (10Aug20-25Aug20) and 2 (14Sep20-10Oct20), subject took medication to treat pain or fever. Please ensure ConMed eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:29:34
Query 'Per CDM: Per Diary Dose 1 (10Aug20-25Aug20) and 2 (14Sep20-10Oct20), subject took medication to treat pain or fever. Please ensure ConMed eCRF is updated accordingly.' answered with 'pt taking norco and ibuprofen prn ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:55:20
User opened query 'Per CDM: Per Diary Dose 1 (10Aug20-25Aug20) and 2 (14Sep20-10Oct20), subject took medication to treat pain or fever. Please ensure ConMed eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:01:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:56:08

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:39:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:39:59
Data point term sent to Coder	System	15 Oct 2020 21:53:01
User entered 'FLECAINIDE' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:52:30
Data point term sent to Coder	System	15 Oct 2020 21:51:59
Coding entries removed.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:51:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:15:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:15:08
Data point term sent to Coder	System	14 Aug 2020 15:00:20
User entered 'Flecainide (PVC)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per CDM: Thank you for your response, however, there is no corresponding entry on the Med History. Please update the page accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:23:57
Query 'Per CDM: Thank you for your response, however, there is no corresponding entry on the Med History. Please update the page accordingly.' answered with 'med history updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:02:04
User opened query 'Per CDM: Thank you for your response, however, there is no corresponding entry on the Med History. Please update the page accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:39:08
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:39:08
Query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Please reconcile with Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:51:58
User entered 'ARRHYTHMIA-PVC' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 21:51:52
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARRHYTHMIA. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:56:05
User entered 'Arrhythmia'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '50'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Q12°'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 23:02:07
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	14 Aug 2020 14:59:43
User entered 'UN May 2016'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 14:59:43

FDA-CBER-2022-1614-0507041

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 14:59:43

FDA-CBER-2022-1614-0507042

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 14:59:43

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 10:19:09
Data point term sent to Coder	System	14 Aug 2020 15:05:29
User entered 'Gabapentin'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of NERVE PAIN, NEURALGIA. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:35:20
Query 'Per DM CLR: Please update the indication to reflect the location/type of NERVE PAIN, NEURALGIA. Please reconcile with Med History eCRF as appropriate. ' answered with 'MED HX UPDATED' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:03:37
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NERVE PAIN, NEURALGIA. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:56:23
User entered 'Nerve Pain, Neuralgia'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '900'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:40:26
User entered 'UN Apr 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:40:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 23:02:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 15:05:22
User entered 'UN UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

FDA-CBER-2022-1614-0507056

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 15:05:22

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE, PRODUCTSYNONYM: PRED FORTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:53:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 13:53:44
Data point term sent to Coder	System	24 Sep 2020 22:56:48
Coding entries removed.	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:56:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISOLONE ACETATE, PRODUCTSYNONYM: PRED FORTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:34:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:34:46
Data point term sent to Coder	System	20 Aug 2020 21:38:58
User entered 'Pred Forte'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

FDA-CBER-2022-1614-0507064

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please reviewn indication to include the specific location of OPHTHALMIC HERPES (e.g. Left, Right, Bilateral). Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 19:17:36
Query 'Per DM CLR: Please reviewn indication to include the specific location of OPHTHALMIC HERPES (e.g. Left, Right, Bilateral). Reconcile and update as appropriate. ' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:56:25
User entered 'OPHTHALMIC HERPES-right eye' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:56:19
User opened query 'Per DM CLR: Please reviewn indication to include the specific location of OPHTHALMIC HERPES (e.g. Left, Right, Bilateral). Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:52:53
User entered 'Ophthalmic Herpes'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Drop, Each Eye'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route (eg. Topical, etc.) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:24:45
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route (eg. Topical, etc.) as appropriate. ' answered with 'This is an eye drop and is administered into the right eye' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	23 Oct 2020 19:03:06
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route (eg. Topical, etc.) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:48:45
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 19:27:15
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:56:31
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	24 Sep 2020 22:56:19
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:53:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:38:46
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:34:44
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'STOP DATE WAS ENTERED IN ERROR. PER SOURCE NOTE CONDITION IS ONGOING ' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:06:39
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:38:46

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIVIRALS, PRODUCT: FAMCICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:29:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:29:13
Data point term sent to Coder	System	20 Aug 2020 18:43:41
User entered 'Famciclovir'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Ophthalmic Herpes Right Eye'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '500'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:43:36
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Aug 2020 18:43:36
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:43:36
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	20 Aug 2020 18:43:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:35:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'STOP DATE WAS RECORDED IN ERROR. PER CHART NOTE CONDITION AND MEDICATION STILL ONGOING' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:07:31
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MedHistory has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:54:40
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:43:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:43:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:43:36
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:43:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:43:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:43:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:43:36
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:43:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:43:24

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:46:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:46:20
Data point term sent to Coder	System	20 Aug 2020 18:45:43
User entered 'Sertraline'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Depression'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '50'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:45:10
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:45:10

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:49:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:49:30
Data point term sent to Coder	System	20 Aug 2020 18:48:48
User entered 'Crestor'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '5'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:48:07
User entered 'UN Feb 2018'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:48:07

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:48:07

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:51:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:51:20
Data point term sent to Coder	System	20 Aug 2020 18:49:50
User entered 'Norco'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Query 'Per DM CLR: Please review indication to include the location of LEG PAIN (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:50:57
User opened query 'Per DM CLR: Please review indication to include the location of LEG PAIN (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:55:37
User entered 'Back and Leg Pain'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '7.5/325'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:49:33

FDA-CBER-2022-1614-0507141

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:49:33
User entered 'UN Aug 2018'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:49:33

FDA-CBER-2022-1614-0507149

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:49:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:23:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 05:23:11
Data point term sent to Coder	System	20 Aug 2020 18:50:53
User entered 'Ibuprofen'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Query 'Per DM CLR: Please review indication to include the location of LEG PAIN (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:53:13
User opened query 'Per DM CLR: Please review indication to include the location of LEG PAIN (i.e. Left, Right, Bilateral). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:56:32
User entered 'Back and Leg Pain'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '800'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:50:33
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:50:33

FDA-CBER-2022-1614-0507168

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:50:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:08:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:08:07
Data point term sent to Coder	System	20 Aug 2020 18:51:56
User entered 'Fish Oil'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Heart Supplement'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '1200'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:51:09
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:51:09

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: QUNOL LIQUID COQ10 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 09:46:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 09:46:43
Data point term sent to Coder	System	20 Aug 2020 18:52:59
User entered 'Qunol'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Heart Supplement'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '100'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:52:11
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:52:11

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:53:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:53:22
Data point term sent to Coder	System	20 Aug 2020 18:53:02
User entered 'Calcium'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Bone Health'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '600'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:53:00
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:00

FDA-CBER-2022-1614-0507221

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:53:00

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: FOSAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:55:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:55:23
Data point term sent to Coder	System	20 Aug 2020 18:54:06
User entered 'Fosamax'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Osteoporosis'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '70'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'every week (QS)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:25:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:53:49
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '803 (803)'	System	20 Aug 2020 18:53:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 06:16:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 06:16:41
Data point term sent to Coder	System	20 Aug 2020 20:16:44
User entered 'OCUVITE' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:15:59
Data point term sent to Coder	System	20 Aug 2020 18:59:20
User entered 'Ocuvite1'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:55:03
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:27:47
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:04:50
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:04:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:04:35
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:12:08
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 18:52:36
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'multiple ingredients in medication, 1 softgel daily' (Site from DM).	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 20:02:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:09:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un May 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:26:31
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	16 Nov 2020 18:26:40
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:26:40
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	16 Nov 2020 18:26:31
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:58:50

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:58:50

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:01:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:01:27
Data point term sent to Coder	System	20 Aug 2020 19:00:26
User entered 'Vitamin D'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:55:12
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 01:00:30
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:05:21
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:05:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:05:09
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:12:27
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '2000'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'IU (IU)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:59:56

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un UNK 2000' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:03
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:03
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:59:56

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 18:59:56

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:59:56

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX WITH VITAMIN C, PRODUCT: ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE, PRODUCTSYNONYM: VITAMIN B COMPLEX WITH C - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 05:49:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 05:49:40
Data point term sent to Coder	System	20 Aug 2020 20:09:34
User entered 'B-Complex with Vitamin C'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un UNK 2010' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:29
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:29
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:09:21

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:09:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:16:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:16:22
Data point term sent to Coder	System	20 Aug 2020 20:10:37
User entered 'CBD Oil'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:55:26
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 01:00:50
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:06:49
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:05:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:05:59
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:12:44
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
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)	23 Feb 2021 03:10:49
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 'this is the correct dosage, is for supplement' (Site from DM).	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 20:03:26
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)	27 Jan 2021 10:09:57
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '20'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:45:37
User closed query 'Source listed down May 2020 as start date. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:45:36
Query 'Source listed down May 2020 as start date. Please verify and update. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:58:48
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:58:43
User entered 'UN May 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:58:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User opened query 'Source listed down May 2020 as start date. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:52:38
User entered 'un Mar 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:57

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:27:48
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:09:57

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication and update dose and dose unit field as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:11:04
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication and update dose and dose unit field as appropriate.' answered with 'Voltaren gel for back and muscle pain' (Site from DM).	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 20:15:28
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple drug strengths for this medication and update dose and dose unit field as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:10:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:29:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 05:29:10
Data point term sent to Coder	System	19 Nov 2020 01:00:02
Coding entries removed.	Matthew Musikanth	19 Nov 2020 00:59:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:58:53

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:06:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:06:16
Data point term sent to Coder	System	20 Aug 2020 20:11:38
User entered 'Voltaren Gel'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

FDA-CBER-2022-1614-0507318

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:52:45
User closed query 'Please verify and provide source for this indication. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:52:43
Query 'Please verify and provide source for this indication. ' answered with 'Source documents medical history of back pain' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:58
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:39
User entered 'Back and MUSCLE PAIN' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:39
User opened query 'Please verify and provide source for this indication. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 23:40:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Query 'Per DM CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Back, Left Thigh, Right Arm, etc.). Reconcile and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:53:27
User opened query 'Per DM CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Back, Left Thigh, Right Arm, etc.). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:58:31
User entered 'Muscle Pain'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '4'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'g (g)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:53:21
User closed query 'Source listed frequency as QID. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:53:19
Query 'Source listed frequency as QID. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:44
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:39
User entered 'four times daily (QID)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:59:39
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User opened query 'Source listed frequency as QID. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:54:18
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

FDA-CBER-2022-1614-0507325

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un Jun 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:10
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:10
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:10:49

FDA-CBER-2022-1614-0507331

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 00:59:39
User entered '2'	System	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:10:49

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:27:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:27:19
Data point term sent to Coder	System	20 Aug 2020 20:12:40
User entered 'Ativan'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

FDA-CBER-2022-1614-0507336

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected long term 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)	23 Feb 2021 03:11:26
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected long term use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'the ativan is for insomnia as needed per pt. ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 17:48:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected long term 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)	27 Jan 2021 10:10:33
User closed query 'Please verify and provide source for this indication. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:49:09
Query 'Please verify and provide source for this indication. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 18:59:26
User opened query 'Please verify and provide source for this indication. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 23:39:30
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Insomnia'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:38

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un UNK 2010' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:32
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:32
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:11:38

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:11:38

FDA-CBER-2022-1614-0507349

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:11:38

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 14:57:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 14:57:00
Data point term sent to Coder	System	19 Nov 2020 19:57:40
Coding entries removed.	Matthew Musikanth (b) (4)	19 Nov 2020 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:08:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:08:16
Data point term sent to Coder	System	22 Aug 2020 16:07:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:14

US3112173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:16:38

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:14
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	22 Aug 2020 16:06:10
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:05:07
Data point term sent to Coder	System	20 Aug 2020 20:14:41
User entered 'Flexeril'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 16:54:57
Query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'medication taken for mhx line 13 and 17' (Site from DM).	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 21:25:04
User opened query 'Per DM CLR: Please note there is no AE matching this Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 04:47:35
Data hard unlocked.	(b) (4), (b) (6)	19 Mar 2021 04:47:29
Data hard locked.	(b) (4), (b) (6)	19 Mar 2021 04:47:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:57:35
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 19:57:01
User entered 'Back and MUSCLE PAIN' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
Query 'Per MD CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Generalized, Back, Left Thigh, etc.). Reconcile and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:53:39
User opened query 'Per MD CLR: Please review the indication to include the specific location of MUSCLE PAIN (e.g. Generalized, Back, Left Thigh, etc.). Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 23:59:58
User entered 'Muscle Pain'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

FDA-CBER-2022-1614-0507356

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '10'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:35:47
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:47:31
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	12 Apr 2021 16:44:49
User entered 'as needed (PRN)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	12 Apr 2021 16:44:49
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
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)	25 Mar 2021 16:55:06
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 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 21:18:47
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 21:18:36
User entered 'three times daily (TID)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	23 Mar 2021 21:18:36
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)	19 Mar 2021 04:47:50
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '19 Oct 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:49
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:28:49
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Source listed a stop date of Dec. 2020. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 17:43:27
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:43:25
Query 'Source listed a stop date of Dec. 2020. Please update EDC. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	23 Feb 2021 23:33:40
DataPoint Un-verified.	Matthew Musikanth (b) (4)	23 Feb 2021 23:33:24
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	23 Feb 2021 23:33:24
User opened query 'Source listed a stop date of Dec. 2020. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 01:03:42
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:43:29
DataPoint Un-verified.	Matthew Musikanth (b) (4)	23 Feb 2021 23:33:24
User entered 'un Dec 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	23 Feb 2021 23:33:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:49
User entered '3'	System	23 Mar 2021 21:18:36
User entered '1'	System	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:49
User entered '1'	System	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:44:49
User entered '804 (804)'	System	20 Aug 2020 20:14:14

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:16:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:16:21
Data point term sent to Coder	System	20 Aug 2020 20:15:43
User entered 'Losartan'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

FDA-CBER-2022-1614-0507373

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
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)	19 Oct 2020 08:02:42
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 'dose corrected' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:59:14
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)	15 Sep 2020 00:00:59
User entered 'Hypertension'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '50' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	14 Oct 2020 22:59:05
User entered '5'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:15:15

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

FDA-CBER-2022-1614-0507378

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'un Mar 2020' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:29:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0' reason for change: Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	16 Nov 2020 18:29:09
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:15:15

FDA-CBER-2022-1614-0507385

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:15:15

FDA-CBER-2022-1614-0507386

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:15:15

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: SEPTRA DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:40:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:40:50
Data point term sent to Coder	System	19 Nov 2020 00:39:51
Coding entries removed.	Matthew Musikanth (b) (4)	19 Nov 2020 00:38:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: SEPTRA DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:18:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:18:33
Data point term sent to Coder	System	15 Oct 2020 22:17:36
User entered 'Septra DS'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Please review indication for Septra DS. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:55:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:33
Query 'Please review indication for Septra DS. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:39:30
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:38:54
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:38:54
User opened query 'Please review indication for Septra DS. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:43:29
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:24:31
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 17:04:07

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 17:04:01
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:14:47
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:43
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:38:54
User entered 'Poor wound healing' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:38:54
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'prophylaxis post op infection'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 80mg/400mg, 160mg/800mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:22:38
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 80mg/400mg, 160mg/800mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	05 Nov 2020 21:29:13
User entered '160/800' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Nov 2020 21:29:00
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 80mg/400mg, 160mg/800mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:16:36
User entered '1'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Nov 2020 21:29:00
User entered 'tablet (TABLET)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Progress note on 17Sep2020 listed dose of Septra DS as 1 tab BID but conmed log lists QID. Please verify dosage and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:56:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:51
User closed query 'Source listed down QID as frequency. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:55:48
Query 'Progress note on 17Sep2020 listed dose of Septra DS as 1 tab BID but conmed log lists QID. Please verify dosage and update accordingly. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:39:38
Query 'Source listed down QID as frequency. Please verify and update. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:39:35
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:39:25
User entered 'twice daily (BID)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:39:25
User opened query 'Progress note on 17Sep2020 listed dose of Septra DS as 1 tab BID but conmed log lists QID. Please verify dosage and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:46:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User opened query 'Source listed down QID as frequency. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:57:32
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '17 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

FDA-CBER-2022-1614-0507401

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '27 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 00:39:25
User entered '1'	System	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 22:17:33

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:46:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:46:19
Data point term sent to Coder	System	19 Nov 2020 00:40:51
Coding entries removed.	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:44:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:44:25
Data point term sent to Coder	System	15 Oct 2020 22:19:39
User entered 'keflex'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:52
User closed query 'Please review indication for Keflex. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:40:51
Query 'Please review indication for Keflex. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:14
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:05
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:05
User opened query 'Please review indication for Keflex. Progress note dated 17Sep2020 states that medication was given because incision was not healing well. Kindly update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:42:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:23:40
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 17:06:21

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 17:06:15
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:11:56
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:59
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:05
User entered 'Poor wound healing' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'prophylaxis post op infection'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '500'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:55:25
User closed query 'Progress note on 17Sep2020 listed dose of Keflex as 1 tab QID but conmed log lists BID. Please verify dosage and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:55:20
Query 'Progress note on 17Sep2020 listed dose of Keflex as 1 tab QID but conmed log lists BID. Please verify dosage and update accordingly. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:18
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:09
User entered 'four times daily (QID)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:40:09
User opened query 'Progress note on 17Sep2020 listed dose of Keflex as 1 tab QID but conmed log lists BID. Please verify dosage and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:47:52
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'twice daily (BID)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '17 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

FDA-CBER-2022-1614-0507420

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

FDA-CBER-2022-1614-0507421

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '01 Oct 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	19 Nov 2020 00:40:09
User entered '2'	System	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 22:19:29

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:14
User closed query 'Source listed down Robaxin. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:40:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:38:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 00:38:50
Data point term sent to Coder	System	19 Nov 2020 00:37:49
Query 'Source listed down Robaxin. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:37:33
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:37:25
User entered 'ROBAXin' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:37:25
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User opened query 'Source listed down Robaxin. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:58:49
Data point term sent to Coder	System	15 Oct 2020 22:21:43
User entered 'robaxix'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:40:18
DataPoint Un-verified.	Matthew Musikanth (b) (4)	19 Nov 2020 00:37:25
User entered 'Pain secondary to spinal fusion' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	19 Nov 2020 00:37:25
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'post operative pain (spinal fusion)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '750'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

FDA-CBER-2022-1614-0507433

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'four times daily (QID)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '24 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:56:55
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:26:52
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:11:08
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:11:01
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:11:01
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 12:13:19
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Source listed 21Sep2020. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 17:44:03
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:44:00
Query 'Source listed 21Sep2020. Please update EDC. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	23 Feb 2021 23:34:52
DataPoint Un-verified.	Matthew Musikanth (b) (4)	23 Feb 2021 23:34:42
User entered '21 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	23 Feb 2021 23:34:42
User opened query 'Source listed 21Sep2020. Please update EDC. ' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 00:56:50
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 00:56:24
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	21 Jan 2021 00:11:01
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	21 Jan 2021 00:10:55
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:10:55
User entered '20 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 00:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:58:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '4'	System	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 22:21:04

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:35:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:35:52
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
Data point term sent to Coder	System	23 Apr 2021 16:47:30
User entered 'Oxycodone'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

FDA-CBER-2022-1614-0507447

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Revision of left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '5'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:46:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:27:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
Data point term sent to Coder	System	23 Apr 2021 16:48:31
User entered 'Meloxicam'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Revision of left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '10'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:47:32

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US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '20 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

FDA-CBER-2022-1614-0507474

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:47:32

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:40:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:40:39
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
Data point term sent to Coder	System	23 Apr 2021 16:48:31
User entered 'Aspirin'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

FDA-CBER-2022-1614-0507482

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Revision of left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '81'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

FDA-CBER-2022-1614-0507486

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

FDA-CBER-2022-1614-0507488

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '20 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

FDA-CBER-2022-1614-0507492

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 09 Jun 2021 15:16:38
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:48:28

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 15:16:38
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:09
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:11:30

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:31
User entered '24 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:13:59

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US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:31
User entered 'Spinal fusion'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:13:59

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
User closed query 'Source indicated that surgery was done due to degenerative disc disease of lumbar spine. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 22:44:23
Query 'Source indicated that surgery was done due to degenerative disc disease of lumbar spine. Please verify and update accordingly.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	19 Nov 2020 00:48:37
User opened query 'Source indicated that surgery was done due to degenerative disc disease of lumbar spine. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:50:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:31
User entered 'Medical History (MH)'	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:13:59

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 15:16:38
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:48:31
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	15 Oct 2020 22:13:59

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:21:02
User entered '18 Feb 2021'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:08:21

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:21:02
User entered 'left hip relocation'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:08:21

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:21:02
User entered 'Adverse Event (AE)'	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:08:21

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 15:16:38
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:10:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:21:02
User entered empty.	Natalie Moy (b) (4) (b) (4)	24 Feb 2021 23:08:21

FDA-CBER-2022-1614-0507508

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered '19 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 16:38:00

FDA-CBER-2022-1614-0507509

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:16:38
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Revision of left hip replacement'	(b) (4), (b) (6)	23 Apr 2021 16:38:00

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:16:38
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	23 Apr 2021 16:38:00

US3112173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 15:16:38
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:02:37
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:38:00

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'USA-US062-2021-MRNA-1273-P301000017'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Yes (Y)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Yes (Y)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Todd'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Simmons'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered '9040 Friars Road Suite 540'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'San Diego'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'CA'	System	26 Apr 2021 18:21:39

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US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered '92108'	System	26 Apr 2021 18:21:39

FDA-CBER-2022-1614-0507526

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
User entered 'US'	System	26 Apr 2021 18:22:03

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:22:03

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'USA-US062-2021-MRNA-1273-P301000017'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Yes (Y)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Yes (Y)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'No (N)'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Todd'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'Simmons'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered '9040 Friars Road Suite 540'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'San Diego'	System	26 Apr 2021 18:21:39

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered 'CA'	System	26 Apr 2021 18:21:39

FDA-CBER-2022-1614-0507541

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:21:55
User entered '92108'	System	26 Apr 2021 18:21:39

FDA-CBER-2022-1614-0507542

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
User entered 'US'	System	26 Apr 2021 18:22:03

FDA-CBER-2022-1614-0507543

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form
Generated On: 09 Jun 2021 15:16:38
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:22:03

US3112173
Folder: SAE USA-US062-2021-MRNA-1273-P301000017
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 15:16:38
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
User entered '26/Apr/2021 14:22'	System	26 Apr 2021 18:22:03

US3112173

Folder: SAE USA-US062-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:16:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	28 Apr 2021 21:49:39
User entered '1'	(b) (4), (b) (6)	26 Apr 2021 18:22:03