US3762175 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:45:00

All time stamps listed in this document are displayed in GMT

Participant ID   US3762175

mRNA-1273-P301 Completion Guidelines

US3762175

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4)　**12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
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

Date of Informed Consent *(dd MMM yyyy)*	3 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020

Protocol Version
- Amendment 1 ○
- Amendment 2 ○
- Amendment 3 ●
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?
- Yes ●
- No ○

If No, indicate reason for screen fail
- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?
- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4)   **12 Feb 2021 23:09:30**

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Did the participant meet all eligibility criteria?   Yes ⬤

No ◯

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4)   **12 Feb 2021 23:09:30**

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Were any significant conditions reported?   Yes ●

No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	TALWIN ALLERGY
Start date (dd MMM yyyy)	01 UNK 1968
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 1968
Start Year (derived)	1968
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	CLINDAMYCIN ALLERGY
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	LEFT ROTATOR CUFF/BICEPS TENDON REPAIR
Start date (dd MMM yyyy)	01 UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	01 UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	MELANOMA IN RIGHT EYE
Start date (dd MMM yyyy)	01 UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	FARSIGHTED
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	GLAUCOMA
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4)   **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	TINNITUS
Start date (dd MMM yyyy)	01 UNK 1957
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 1957
Start Year (derived)	1957
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	RETINOPOTHY IN RIGHT EYE
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	CATARACTS
Start date (dd MMM yyyy)	01 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	HEARING LOSS
Start date (dd MMM yyyy)	01 UNK 1961
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 1961
Start Year (derived)	1961
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	PNEUMONIA
Start date (dd MMM yyyy)	01 UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ⭕
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	01 UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	HIGH TRIGLYCERIDES
Start date (dd MMM yyyy)	01 UNK 1988
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 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

Condition	UNSTEADY GAIT
Start date (dd MMM yyyy)	01 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	SHINGLES
Start date (dd MMM yyyy)	01 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ⭕
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	01 UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	PERIPHERAL VASCULAR DISEASE IN LEFT LEG
Start date (dd MMM yyyy)	01 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	DEPRESSION
Start date (dd MMM yyyy)	01 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	FREQUENT NIGHTTIME URINATION
Start date (dd MMM yyyy)	01 UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	DECREASED LIBIDO
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	ARTHRITIS
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	RECURREMT JOINT PAIN
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	01 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)	

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	GASTRITIS
Start date (dd MMM yyyy)	01 UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Condition	CHRONIC BACK PAIN
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)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	12:54 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:54
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	228 lb
BMI *(xxx.x)*	31.86604 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?   Yes ⬤

                                                                             No ◯

Date of examination *(dd MMM yyyy)*   03 SEP 2020

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

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Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 23:09:30**
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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ◯ No ⬤
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ◯ No ⬤
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ◯ No ⬤
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ◯ No ⬤
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ◯ No ⬤
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ◯ No ⬤
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ◯ No ⬤
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ◯ No ⬤
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ◯ No ⬤
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ◯ No ⬤
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ◯ No ⬤
Other	Yes ◯ No ⬤

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **12 Feb 2021 23:09:30**

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

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Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 23:09:31**
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ●
	Clinic ○
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

What was the date of randomization? *(dd MMM yyyy)*	03 SEP 2020
What was the participant's randomization number?	189730

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 ●	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

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)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	12:54 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:54
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

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)*	03 SEP 2020
Time of assessment *(00:00-23:59)*	14:39 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:39
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

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.

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)*	3 SEP 2020
What was the treatment time? *(00:00-23:59)*	14:02 (24 HR)
Treatment Date and Time (derived)	3 SEP 2020 14:02
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

US3762175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	03 SEP 2020
Collection time *(00:00-23:59)*	13:43 (24 HR)
Collection date and time (derived)	03 SEP 2020 13:43

US3762175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*			03 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:44	03 SEP 2020 13:44
Nasopharyngeal Swab 2	No		

US3762175

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag	1

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	03 SEP 2020 16:48
PC Open Date & Time	03 SEP 2020 14:22
PC Close Date & Time	03 SEP 2020 16:52

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

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):

PC Time Stamp	04 SEP 2020 06:59
PC Open Date & Time	03 SEP 2020 17:47
PC Close Date & Time	04 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 11:50
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-3338229

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 21:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	06 SEP 2020 21:43
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

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**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	07 SEP 2020 21:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 20:57
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 21:29
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

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	03 SEP 2020 16:49
PC Open Date & Time	03 SEP 2020 14:22
PC Close Date & Time	03 SEP 2020 16:52

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

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	04 SEP 2020 07:02
PC Open Date & Time	03 SEP 2020 17:47
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-3338236

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00

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	05 SEP 2020 11:50
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

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	05 SEP 2020 21:55
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

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	06 SEP 2020 21:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00

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	07 SEP 2020 21:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

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	08 SEP 2020 20:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00

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	09 SEP 2020 21:29
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

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 ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	03 SEP 2020 16:50
PC Open Date & Time	03 SEP 2020 14:22
PC Close Date & Time	03 SEP 2020 16:52

FDA-CBER-2022-1614-3338244

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	○

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ● |
| | Yes ○ |

PC Time stamp	04 SEP 2020 07:03
PC Open Date & Time	03 SEP 2020 17:47
PC Close Date & Time	04 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00

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 ●

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00

	Yes ◯
PC Time stamp	05 SEP 2020 11:51
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00

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	05 SEP 2020 21:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00

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 ⬤

	Yes ◯
PC Time stamp	06 SEP 2020 21:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

TIMEPOINT	DAY 5

HEADACHE

None	⬤
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	⬤
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	⬤
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00

	Yes ◯
PC Time stamp	07 SEP 2020 21:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

TIMEPOINT	DAY 6
HEADACHE	None ●
	No interference with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
FATIGUE	None ●
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ◯
	Some interference with activity or >2 episodes/24 hours ◯
	Prevents daily activity, requires outpatient IV hydration ◯
CHILLS	None ●
	No interference with activity ◯
	Some interference with activity not requiring medical attention ◯
	Prevents daily activity and requires medical attention ◯
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

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	Yes ◯
PC Time stamp	08 SEP 2020 20:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

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

	Yes ◯
PC Time stamp	09 SEP 2020 21:30
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3762175
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 23:09:30**
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?   Yes ⬤

No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   10 SEP 2020

Please select one status for the follow-up contact   Contact Made ⬤

Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3762175

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?　　　　Yes ●

　　　　No ○

Continuing Flag　　　　1

US3762175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

| 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

US3762175

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit? Yes ●

No ◯

Continuing Flag 1

US3762175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 25 SEP 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3762175

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3762175
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 23:09:31**
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT2

Timepoint	Pre-Dose ●
	Post-Dose ○

Were vital signs assessed?	Yes ●
	No ○

Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	11:06 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 11:06
Temperature *(xxx.x)*	98.8 F

Route of measurement	Oral ●
	Axillary ○
	Other ○

If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Timepoint	Pre-Dose ⦾
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⦾
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	12:24 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:24
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ⬤
	Axillary ⦾
	Other ⦾
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3762175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   01 OCT 2020

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

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)*	1 OCT 2020
What was the treatment time? *(00:00-23:59)*	11:45 (24 HR)
Treatment Date and Time (derived)	1 OCT 2020 11:45
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-2022-1614-3338269

US3762175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	01 OCT 2020
Collection time *(00:00-23:59)*	11:19 (24 HR)
Collection date and time (derived)	01 OCT 2020 11:19

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*			01 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:22	01 OCT 2020 11:22
Nasopharyngeal Swab 2	No		

US3762175
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 23:09:31**
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?　　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	01 OCT 2020 12:29
PC Open Date & Time	01 OCT 2020 12:05
PC Close Date & Time	01 OCT 2020 14:35

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	02 OCT 2020 00:14
PC Open Date & Time	01 OCT 2020 15:30
PC Close Date & Time	02 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	02 OCT 2020 20:33
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ○

Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	03 OCT 2020 21:26
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

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US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

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**	98.4 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	04 OCT 2020 16:50
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	05 OCT 2020 21:15
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-3338278

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Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

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**	98.1 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	06 OCT 2020 22:48
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 OCT 2020 23:17
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

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	01 OCT 2020 12:30
PC Open Date & Time	01 OCT 2020 12:05
PC Close Date & Time	01 OCT 2020 14:35

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	02 OCT 2020 00:16
PC Open Date & Time	01 OCT 2020 15:30
PC Close Date & Time	02 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ◯
	Does not interfere with activity ⬤
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⬤
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	50
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	02 OCT 2020 20:38
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00

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.	30

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.	130

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	03 OCT 2020 21:36
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ○
	Does not interfere with activity ●
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ●
	No ○

Please record - **REDNESS AT INJECTION SITE (in mm)**	10

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)**	135

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	04 OCT 2020 16:51
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**	110
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	05 OCT 2020 21:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	95

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	06 OCT 2020 22:48
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	45
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	07 OCT 2020 23:17
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

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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US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	01 OCT 2020 12:31
PC Open Date & Time	01 OCT 2020 12:05
PC Close Date & Time	01 OCT 2020 14:35

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

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

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	02 OCT 2020 00:17
PC Open Date & Time	01 OCT 2020 15:30
PC Close Date & Time	02 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00

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 ●

	Yes ◯
PC Time stamp	02 OCT 2020 20:48
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00

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	03 OCT 2020 21:38
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00

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 ●

	Yes ◯
PC Time stamp	04 OCT 2020 16:52
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

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 ●

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	Yes ◯
PC Time stamp	05 OCT 2020 21:20
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00

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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US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00

	Yes ⬭
PC Time stamp	06 OCT 2020 22:49
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00

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 ●

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	Yes ◯
PC Time stamp	07 OCT 2020 23:18
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 8
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⬤
	No ◯
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**	5

Measure the largest size across any injection site swelling/hardness with the ruler provided.

PC Time stamp	08 OCT 2020 17:17
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

TIMEPOINT	DAY 9
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
PC Time stamp	09 OCT 2020 18:17
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	08 OCT 2020 17:17
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	09 OCT 2020 18:18
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3762175
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 23:09:30**
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?   Yes ●

                                                              No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   08 OCT 2020

Please select one status for the follow-up contact   Contact Made ●

                                                   Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3762175

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3762175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 OCT 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3762175
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 23:09:30**
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3762175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4)   **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3762175

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:30**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit? Yes ●

No ◯

Continuing Flag 1

US3762175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT3

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	05 NOV 2020
Time of assessment *(00:00-23:59)*	11:22 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 11:22
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3338316

US3762175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

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.

US3762175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4)   **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	05 NOV 2020
Collection time *(00:00-23:59)*	11:33 (24 HR)
Collection date and time (derived)	05 NOV 2020 11:33

US3762175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **12 Feb 2021 23:09:31**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	05 NOV 2020 11:18:55
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	11 NOV 2020 19:56:27
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	18 NOV 2020 20:23:04
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 20:43:42
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 11:26:46
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 11:04:02
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	12 DEC 2020 18:29:35
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯
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	19 DEC 2020 01:54:20
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

FDA-CBER-2022-1614-3338327

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	26 DEC 2020 21:32:25
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	02 JAN 2021 22:55:13
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	09 JAN 2021 22:12:24
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Date and time of submission	16 JAN 2021 16:37:01
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

FDA-CBER-2022-1614-3338331

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	25 JAN 2021 21:48:32
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	31 JAN 2021 23:07:58
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ●
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ●
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Date and time of submission	06 FEB 2021 15:24:46
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

FDA-CBER-2022-1614-3338334

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	13 FEB 2021 20:36:40
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	21 FEB 2021 23:58:07
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	28 FEB 2021 14:19:56
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	06 MAR 2021 18:06:20
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	13 MAR 2021 14:12:09
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 17:14:48
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

FDA-CBER-2022-1614-3338340

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	27 MAR 2021 16:04:26
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	03 APR 2021 10:20:21
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	10 APR 2021 23:09:45
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	18 APR 2021 17:35:49
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	26 APR 2021 17:52:53
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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	02 MAY 2021 20:26:17
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

FDA-CBER-2022-1614-3338349

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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-2022-1614-3338351

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338353

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338355

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338359

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338361

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ⬭

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ○

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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 ⚪

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338371

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 JUL 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338373

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338375

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338377

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338379

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338381

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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 ◯

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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 ⚪

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338387

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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-2022-1614-3338389

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338391

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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-2022-1614-3338393

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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 ⬭

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

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 ◯

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338399

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338401

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ⚪

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT <div align="right">DAY 453</div>

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):

Symptom	
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-2022-1614-3338405

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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-2022-1614-3338407

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ○

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	**DAY 474**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

FDA-CBER-2022-1614-3338411

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338415

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338417

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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-2022-1614-3338419

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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-2022-1614-3338421

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338423

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
Fever (Temperature $\geq$ 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-2022-1614-3338425

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ○

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338433

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338435

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT	**DAY 565**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

FDA-CBER-2022-1614-3338437

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ⃝

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338441

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338443

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ⭕

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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-2022-1614-3338447

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	04 MAY 2022 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	11 MAY 2022 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ⚪

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338455

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338457

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338459

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338465

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338467

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338471

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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-2022-1614-3338477

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

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 $\geq$ 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-2022-1614-3338479

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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 ⚪

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338485

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
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-2022-1614-3338487

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338489

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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):

Symptom	
Fever (Temperature $\geq$ 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 ⭘

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 $\geq$ 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-2022-1614-3338493

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ⬭

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯

FDA-CBER-2022-1614-3338499

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ⃝

FDA-CBER-2022-1614-3338501

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 ◯ |

FDA-CBER-2022-1614-3338503

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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

US3762175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:45:00

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		05 MAR 2021 18:36:04	

US3762175
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **08 Mar 2021 18:33:09**
Generated On: 10 Jun 2021 09:45:00

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 25 NOV 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3762175

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **08 Mar 2021 18:33:09**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ⬤

                                                               No ◯

Continuing Flag   1

US3762175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3762175
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3762175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?	Yes ⬤
	No ⭕
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 JAN 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ⭕

Comments

If Contact Not Made, please provide Comments _____

US3762175

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ●

                                                                                No ◯

Continuing Flag   1

US3762175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

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 _____

US3762175

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3762175
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3762175
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?   Yes ◯

                                                                        No ⬤

Date of assessment *(dd MMM yyyy)* _____

Time of assessment *(00:00-23:59)* _____

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

   Route of measurement   Oral ◯

                                                                        Axillary ◯

                                                                        Other ◯

   If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

FDA-CBER-2022-1614-3338515

US3762175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

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.

Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	9 APR 2021
Collection time *(00:00-23:59)*	10:31 (24 HR)
Collection date and time (derived)	9 APR 2021 10:31

US3762175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3762175
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

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   _____

Is the participant continuing to the next visit?   Yes ⬭

                                                                                 No ⬭

Continuing Flag

US3762175
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:00

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact	Clinic Visit - Scheduled ◯
	Clinical Visit - Unscheduled ◯
	Safety Call ◯
	Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?	Yes ◯
	No ◯

Generate Next COVID-19 Assessment   Yes ◯

                                                                     No ◯

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4)   **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ⬤
	No ⭘
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ⭘
	Amendment 6 or later ⬤
Date of unblinding *(dd MMM yyyy)*	19 JAN 2021
Participant randomization assignment	mRNA-1273 ⬤
	Placebo ⭘
Actual Dose 1	mRNA-1273 ⬤
	Placebo ⭘
	Not Administered ⭘
Actual Dose 2	mRNA-1273 ⬤
	Placebo ⭘
	Not Administered ⭘
Will participant receive mRNA-1273?	Yes ⭘
	No ⬤
Placebo Only Flag	
Continuing with mRNA-1273	

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00-23:59)*	10:12 (24 HR)
Collection date and time (derived)	19 JAN 2021 10:12

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00 - 23:59)*	10:14
Collection Date and Time (derived)	19 JAN 2021 10:14

US3762175

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **23 Mar 2021 17:31:26**

Generated On: 10 Jun 2021 09:45:00

Did the participant experience any adverse events?　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　No ○

If Yes, enter details on the Adverse Events form.

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **23 Mar 2021 17:31:25**

Generated On: 10 Jun 2021 09:45:00

AEID	
Adverse event	INJECTION SITE PAIN
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)*	05 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)*	05 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 ⬭
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ⚪
	Related ⬤
	Not Applicable ⚪

Relationship to Study Procedure	
	Not Related ⚪
	Related ⬤
	Not Applicable ⚪

Action taken with investigational product	
	None ⬤
	Dose Delayed ⚪
	Investigational Product Withdrawn ⚪
	Not Applicable ⚪

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ⚪
	Not Recovered/Not Resolved ⚪
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ⚪
	Recovering/Resolving ⚪
	Unknown ⚪

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **23 Mar 2021 17:31:25**

Generated On: 10 Jun 2021 09:45:00

AEID	
Adverse event	RIGHT AXILLARY LYMPHADENOPATHY CONTRALATERAL INJECTION SITE

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)*	04 SEP 2020
Start time *(00:00-23:59)*	00:00 (24 HR)
AE start date and time (derived)	04 SEP 2020 00:00

Ongoing?
- Yes ◯
- No ●

If not Ongoing, end date *(dd MMM yyyy)*	05 SEP 2020
End time *(00:00-23:59)*	23:59 (24 HR)
AE End Date and Time (derived)	05 SEP 2020 23:59

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **23 Mar 2021 17:31:25**

Generated On: 10 Jun 2021 09:45:00

AEID	USA-US130-2020-MRNA-1273-P30 1000003
Adverse event	BILATERAL LOWER EXTREMITY WEAKNESS

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)*   15 DEC 2020

Start time *(00:00-23:59)*

AE start date and time (derived)

Ongoing?   Yes ◯   No ⬤

If not Ongoing, end date *(dd MMM yyyy)*   18 DEC 2020

End time *(00:00-23:59)*

AE End Date and Time (derived)

Severity   Grade 1/Mild ◯   Grade 2/Moderate ◯   Grade 3/Severe ⬤   Grade 4 ◯

Is the adverse event serious?   Yes ⬤   No ◯

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	16 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	18 DEC 2020

Admitted to ICU?   Yes ◯   No ⬤   Unknown ◯

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **23 Mar 2021 17:31:25**

Generated On: 10 Jun 2021 09:45:00

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **23 Mar 2021 17:31:25**

Generated On: 10 Jun 2021 09:45:00

1.)INTRATHECAL PULL IS
REFILLED ON 14DEC2020 WITH
CLONODINE, BUPIVICAINE,
AND MORPHINE. PATIENT
REPORTS WEAKNESS
FOLLOWING PREVIOUS REFILL
AS WELL.
2.) PART OF SPINE REVEALED
NO CORD COMPRESSION OR
EVIDENCE OF TRANSVERSE
MYELITIS.
3.) NEUROLOGIC EXAM WAS
NORMAL EXCEPT FOR HIS
VIBRATION AND TOUCH IN
TOES
4.) WEAKNESS ATTRIBUTED TO
DEHYDRATION AND
PRESUMABLY NEW PUMP
MEDICATION

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

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) 23 Mar 2021 17:31:25
Generated On: 10 Jun 2021 09:45:00

AEID	
Adverse event	SWELLING AT INJECTION SITE

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)*	2 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ◯ No ⬤

If not Ongoing, end date *(dd MMM yyyy)*	8 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	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ◯
	Related ●
	Not Applicable ◯

Relationship to Study Procedure	Not Related ◯
	Related ●
	Not Applicable ◯

Action taken with investigational product	None ●
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ◯

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Were any prior/concomitant medications and/or vaccinations taken?   Yes ●

No ◯

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

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	GABAPENTIN

Prophylaxis — Yes ◯   No ⬤

Indication	PVD
Dose per administration	300

Dose unit — mg ⬤   ug ◯   mL ◯   g ◯   IU ◯   tablet ◯   capsule ◯   puff ◯   Other ◯

If dose unit is Other, specify _____

Frequency — once daily ◯   twice daily ◯   three times daily ⬤   four times daily ◯   every other day ◯   every week ◯   every month ◯   as needed ◯   once ◯   unknown ◯   other ◯

If frequency is Other, specify _____

Route of administration — Oral ⬤   Topical ◯   Subcutaneous ◯   Transdermal ◯   Intraocular ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **12 Apr 2021 18:37:00**
Generated On: 10 Jun 2021 09:45:00

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 UNK 2016
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	14 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	OMEPRAZOLE

Prophylaxis	Yes ⚪
	No ⚫

Indication	GASTRITIS

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)*	01 UNK 2016
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	01 UNK 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	CILOSTAZOL

Prophylaxis	Yes ◯
	No ⬤

Indication	PVD
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)*	01 UNK 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

FDA-CBER-2022-1614-3338543

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	SIMVOSTATIN

Prophylaxis

Yes ○
No ●

Indication	HIGH CHOLESTEROL
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)*	01 UNK 1988
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	01 UNK 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-3338545

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	DESVENLAFAXINE

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 ○

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EAB) (1725)

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FDA-CBER-2022-1614-3338546

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 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 ●

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ⭕
	No ⬤
Indication	GASTRITIS
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 ⭕

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 UNK 2020
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●

Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Name of Medication	FUROSEMIDE

Prophylaxis	Yes ○
	No ●

Indication	EDEMA LEGS

Dose per administration	40

Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○

If dose unit is Other, specify	

Frequency	once daily ●
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ○

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: [(b) (4)] **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	PROVASTATIN
Prophylaxis	Yes ◯
	No ●
Indication	HIGH CHOLESTEROL
Dose per administration	40
Dose unit	mg ●
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ●
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	AMLODIPINE

Prophylaxis

Yes ◯

No ⬤

Indication	HIGH BLOOD PRESSURE
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)*	01 UNK 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	TRIAZOLAM

Prophylaxis

Yes ⚪

No ⚫

Indication	DEPRESSION
Dose per administration	.25

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify

Frequency

once daily ⚫
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚪
once ⚪
unknown ⚪
other ⚪

If frequency is Other, specify

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

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EAB) (1725)

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 SEP 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 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	VITAMIN E
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
Dose per administration	400

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)*	
Start date completely unknown	True
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 ⬤

FDA-CBER-2022-1614-3338559

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: [(b) (4)] **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	VITAMIN D3
Prophylaxis	Yes ●
	No ○
Indication	SUPPLEMENT
Dose per administration	5000
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)*	
Start date completely unknown	True
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 ⬤

FDA-CBER-2022-1614-3338561

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: ▨ (b) (4) ▨ **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	OMEGA 3-6-9
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 ○

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

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)*	
Start date completely unknown	True
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	LUTENE

Prophylaxis	Yes ⬤
	No ◯

Indication	EYE HEALTH

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 ◯

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4)   **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	VITAMIN B12
Prophylaxis	Yes ⬤
	No ◯
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ◯
	ug ⬤
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ◯
If dose unit is Other, specify	
Frequency	once daily ⬤
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ◯
	once ◯
	unknown ◯
	other ◯
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

	Intramuscular ◯
	Respiratory (Inhalation) ◯
	Intralesional ◯
	Intraperiteoneal ◯
	Nasal ◯
	Vaginal ◯
	Rectal ◯
	Intravenous ◯
	Intravenous Bolus ◯
	Intravenous Drip ◯
	Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	True
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 ●

FDA-CBER-2022-1614-3338567

Name of Medication	ASPIRIN

Prophylaxis	Yes ⚪
	No ⬤

Indication	PVD

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	CYCLOBENZAPRINE
Prophylaxis	Yes ⚪
	No ⚫
Indication	CHRONIC BACK 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)*	UN AUG 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 ●

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	MORPHINE SULFATE

Prophylaxis

Yes ◯

No ⬤

Indication	CHRONIC BACK PAIN
Dose per administration	0.6498

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	DAILY

Route of administration

Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

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EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperitoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	⬤

If route of administration is Other, specify	INTRATHECAL
Start date *(dd MMM yyyy)*	UN UNK 1999
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	CLONODINE
Prophylaxis	Yes ◯
	No ⬤
Indication	CHRONIC BACK PAIN
Dose per administration	26.09
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	DAILY
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	INTRATHECAL
Start date *(dd MMM yyyy)*	UN UNK 1999
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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **12 Apr 2021 18:37:00**
Generated On: 10 Jun 2021 09:45:00

Name of Medication	BUPIVICAINE

Prophylaxis

Yes ◯
No ●

Indication	CHRONIC BACK PAIN
Dose per administration	1.1

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	DAILY

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	INTRATHECAL
Start date *(dd MMM yyyy)*	UN UNK 1999
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	TUMERIC ROOT EXTRACT

Prophylaxis

Yes ⭕
No ⬤

Indication	OSTEOARTHRITIS
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 ⭕

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Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Name of Medication	GABAPENTIN

Prophylaxis
- Yes ◯
- No ⬤

Indication	PVD
Dose per administration	300

Dose unit
- mg ⬤
- ug ◯
- mL ◯
- g ◯
- IU ◯
- tablet ◯
- capsule ◯
- puff ◯
- Other ◯

If dose unit is Other, specify _____

Frequency
- once daily ◯
- twice daily ⬤
- three times daily ◯
- four times daily ◯
- every other day ◯
- every week ◯
- every month ◯
- as needed ◯
- once ◯
- unknown ◯
- other ◯

If frequency is Other, specify _____

Route of administration
- Oral ⬤
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	14 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Were any concomitant procedures performed?   Yes ●

No ○

If yes, please complete Concomitant Procedures form.

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **12 Apr 2021 18:37:00**

Generated On: 10 Jun 2021 09:45:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 JAN 2021	CENTRAL NERVOUS SYSTEM INPLANT / PVD	Medical History	
4 FEB 2021	"NEVRO" - PERMANENT WIRES / PVD	Medical History	

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 _____

US3762175
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:00

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 ◯

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 18:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/DEC/2020 21:16
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

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Data signed: (b) (4) **12 Apr 2021 18:37:31**
Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 13:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/JAN/2021 14:30
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

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) **12 Apr 2021 18:37:31**

Generated On: 10 Jun 2021 09:45:00

SAEID	USA-US130-2020-MRNA-1273-P30 1000003
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/FEB/2021 08:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3762175 (Prod: Wake Forest University Health Sciences)

US3762175

Form: Participant Creation

Generated On: 10 Jun 2021 09:45:00

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'US3762175'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:09:33

US3762175
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:50:02

US3762175

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:09:34

US3762175

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Clinic (Clinic)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:50:02

US3762175
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'SCRN'	System	29 Sep 2020 15:50:02

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:09:34

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Per CDM: Please complete the form' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:32:00
Query 'Per CDM: Please complete the form' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:11:15
User entered '81'	(b) (4), (b) (6)	11 Sep 2020 18:11:09
User opened query 'Per CDM: Please complete the form' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:48:25

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'YEARS'	System	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '81'	System	03 Sep 2020 18:13:06

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Male (M)'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:00

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:00
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:11:09

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Sep 2020'	System	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2020'	System	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:13:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 18:13:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 18:13:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 18:13:06
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:00

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:09:34

US3762175

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:00

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1'	System	03 Sep 2020 18:13:17
User entered empty.	System	03 Sep 2020 18:13:06

US3762175

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:45:00

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:11:20

US3762175

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:45:00

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:51:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:16:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:16:42
Data point term sent to Coder	System	29 Sep 2020 15:57:43
User entered 'talwin allergy'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

FDA-CBER-2022-1614-3338625

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1968'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

FDA-CBER-2022-1614-3338629

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1968'	System	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1968'	System	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 15:57:24

US3762175
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 15:57:24

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
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)	29 Sep 2020 15:59:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:59:43
Data point term sent to Coder	System	29 Sep 2020 15:58:45
User entered 'clindamycin allergy'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

FDA-CBER-2022-1614-3338639

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 15:58:01

US3762175
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:00
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 15:58:01

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:20:21
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 09:20:21
Query 'Per DM CLR: Please note, there is a medical condition if Osteoarthritis (MH #23) and ARTHRITIS (MH #24). Please confirm if this is the underlying condition for this procedure. Otherwise, ensure that the underlying condition for this procedure is recorded. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:21:44
User opened query 'Per DM CLR: Please note, there is a medical condition if Osteoarthritis (MH #23) and ARTHRITIS (MH #24). Please confirm if this is the underlying condition for this procedure. Otherwise, ensure that the underlying condition for this procedure is recorded. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:47:50
Data point term sent to Coder	System	29 Sep 2020 15:59:46
User entered 'left rotator cuff/biceps tendon repair'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 15:59:11

US3762175
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 15:59:11

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
Query 'Per DM CLR: Please note, there is a medical condition if Osteoarthritis (MH #23) and ARTHRITIS (MH #24). Please confirm if this is the underlying condition for this procedure. Otherwise, ensure that the underlying condition for this procedure is recorded. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:21:30
User opened query 'Per DM CLR: Please note, there is a medical condition if Osteoarthritis (MH #23) and ARTHRITIS (MH #24). Please confirm if this is the underlying condition for this procedure. Otherwise, ensure that the underlying condition for this procedure is recorded. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:48:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:00:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:00:44
Data point term sent to Coder	System	29 Sep 2020 15:59:49
User entered 'right rotator cuff repair'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2018'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

FDA-CBER-2022-1614-3338656

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2018'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2018'	System	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2018'	System	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2018'	System	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2018'	System	29 Sep 2020 15:59:39

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:55:52
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 00:55:52
Data point term sent to Coder	System	29 Sep 2020 16:00:49
User entered 'melanoma in right eye'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2014'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2014'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:00:08

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US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2014'	System	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2014'	System	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2014'	System	29 Sep 2020 16:00:08

US3762175

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2014'	System	29 Sep 2020 16:00:08

US3762175
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:00
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:03:42
Data point term sent to Coder	System	29 Sep 2020 16:02:52
User entered 'farsighted'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2016'	System	29 Sep 2020 16:02:00

US3762175
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:00
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2016'	System	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:00

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:31:22
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:54:07
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:03:42
Data point term sent to Coder	System	29 Sep 2020 16:02:52
User entered 'glaucoma'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2016'	System	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2016'	System	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:21

US3762175
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:21

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:04:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:04:44
Data point term sent to Coder	System	29 Sep 2020 16:03:53
User entered 'tinnitus'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1957'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

FDA-CBER-2022-1614-3338696

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1957'	System	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1957'	System	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:59

FDA-CBER-2022-1614-3338703

US3762175
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:02:59

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Retinopathy, LLT: Retinopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:19:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:19:48
Data point term sent to Coder	System	29 Sep 2020 16:03:53
User entered 'retinopothy in right eye'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2016'	System	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2016'	System	29 Sep 2020 16:03:29

US3762175
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:03:29

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:21
Data point term sent to Coder	System	29 Sep 2020 16:04:57
User entered 'cataracts'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Feb 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Feb 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Feb 2020'	System	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2020'	System	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Feb 2020'	System	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2020'	System	29 Sep 2020 16:04:12

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:05:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:05:34
Data point term sent to Coder	System	29 Sep 2020 16:04:57
User entered 'hearing loss'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1961'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1961'	System	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1961'	System	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:04:30

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:05:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:05:33
Data point term sent to Coder	System	29 Sep 2020 16:04:57
User entered 'pneumonia'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 16:04:51

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:37
Data point term sent to Coder	System	29 Sep 2020 16:06:00
User entered 'high cholesterol'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1988'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1988'	System	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1988'	System	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:05:15

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglycerides high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:06:37
Data point term sent to Coder	System	29 Sep 2020 16:05:58
User entered 'high triglycerides'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:00
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1988'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1988'	System	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1988'	System	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:05:34

US3762175
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:05:34

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Gait disturbances, PT: Gait disturbance, LLT: Unsteady gait - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:07:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:07:42
Data point term sent to Coder	System	29 Sep 2020 16:07:01
User entered 'unsteady gait'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:06:05

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:07:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:07:41
Data point term sent to Coder	System	29 Sep 2020 16:07:02
User entered 'shingles'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

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US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:06:27

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
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)	29 Sep 2020 16:07:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:07:41
Data point term sent to Coder	System	29 Sep 2020 16:07:02
User entered 'hypertension'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2016'	System	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2016'	System	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:06:46

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:05:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 13:05:55
Data point term sent to Coder	System	29 Sep 2020 16:08:05
User entered 'peripheral vascular disease in left leg'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:07:44

US3762175
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:45:00
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:07:44

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
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)	29 Sep 2020 16:08:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 16:08:45
Data point term sent to Coder	System	29 Sep 2020 16:08:05
User entered 'depression'	James Lovette (b) (4)	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:04

FDA-CBER-2022-1614-3338809

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:08:04

US3762175
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:08:04

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Nocturia, LLT: Nocturia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:09:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:09:35
Data point term sent to Coder	System	29 Sep 2020 16:09:06
User entered 'frequent nighttime urination'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

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US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2000'	System	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2000'	System	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:08:49

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Psychiatric disorders, HLGT: Sexual dysfunctions, disturbances and gender identity disorders, HLT: Sexual desire disorders, PT: Libido decreased, LLT: Libido decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:10:40
Data point term sent to Coder	System	29 Sep 2020 16:10:07
User entered 'decreased libido'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1999'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

FDA-CBER-2022-1614-3338827

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1999'	System	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1999'	System	29 Sep 2020 16:09:08

US3762175
Folder: Screening
Form: Medical History (22)
Generated On: 10 Jun 2021 09:45:00
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:08

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
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)	29 Sep 2020 16:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:10:40
Data point term sent to Coder	System	29 Sep 2020 16:10:07
User entered 'osteoarthritis'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1999'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

FDA-CBER-2022-1614-3338839

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:25

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1999'	System	29 Sep 2020 16:09:25

US3762175
Folder: Screening
Form: Medical History (23)
Generated On: 10 Jun 2021 09:45:00
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1999'	System	29 Sep 2020 16:09:25

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:25

US3762175

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:25

US3762175
Folder: Screening
Form: Medical History (24)
Generated On: 10 Jun 2021 09:45:00
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Please note that Osteoarthritis start date 01 UNK 1999, please confirm if this is a duplicate. If yes, please ensure only one entry is recorded and update medical history diagnosis as appropriate. KIndly ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:52:53
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Please note that Osteoarthritis start date 01 UNK 1999, please confirm if this is a duplicate. If yes, please ensure only one entry is recorded and update medical history diagnosis as appropriate. KIndly ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:50:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:10:40
Data point term sent to Coder	System	29 Sep 2020 16:10:07
User entered 'arthritis'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1999'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

FDA-CBER-2022-1614-3338849

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1999'	System	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1999'	System	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:41

US3762175

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:09:41

US3762175
Folder: Screening
Form: Medical History (25)
Generated On: 10 Jun 2021 09:45:00
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
Query 'Per DM CLR: Please specify the location of Joint Pain. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:52:56
User opened query 'Per DM CLR: Please specify the location of Joint Pain. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 01:54:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:20:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:20:36
Data point term sent to Coder	System	29 Sep 2020 16:10:07
User entered 'recurremt joint pain'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2019'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

FDA-CBER-2022-1614-3338856

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2019'	System	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2019'	System	29 Sep 2020 16:10:00

US3762175
Folder: Screening
Form: Medical History (25)
Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:10:00

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:12:41
Data point term sent to Coder	System	29 Sep 2020 16:11:08
User entered 'erectile dysfunction'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 1999'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1999'	System	29 Sep 2020 16:10:24

US3762175
Folder: Screening
Form: Medical History (26)
Generated On: 10 Jun 2021 09:45:00
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1999'	System	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	29 Sep 2020 16:10:24

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:31:47
Data point term sent to Coder	System	03 Dec 2020 20:31:05
User entered 'GASTRITIS'	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '01 UNK 2016'	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 2016'	System	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '2016'	System	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	03 Dec 2020 20:30:02

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:18:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:18:01
Data point term sent to Coder	System	22 Jan 2021 17:17:12
User entered 'Chronic back pain'	(b) (4), (b) (6)	22 Jan 2021 17:17:09

US3762175
Folder: Screening
Form: Medical History (28)
Generated On: 10 Jun 2021 09:45:00
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'UN UNK 1999'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'Jan 1999'	System	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:45:00

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '1999'	System	22 Jan 2021 17:17:09

US3762175
Folder: Screening
Form: Medical History (28)
Generated On: 10 Jun 2021 09:45:00
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	22 Jan 2021 17:17:09

US3762175
Folder: Screening
Form: Medical History (28)
Generated On: 10 Jun 2021 09:45:00

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered empty.	System	22 Jan 2021 17:17:09

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '12:54'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '03 Sep 2020 12:54'	System	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '71' in	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59
DataPoint set to visible.	System	03 Sep 2020 18:13:17

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '228' lb	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59
DataPoint set to visible.	System	03 Sep 2020 18:13:17

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered '31.86604'	System	29 Sep 2020 16:11:59
DataPoint set to visible.	System	03 Sep 2020 18:13:17

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'kg/m2'	System	29 Sep 2020 16:11:59
DataPoint set to visible.	System	03 Sep 2020 18:13:17

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'bpm'	System	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'breaths/min'	System	29 Sep 2020 16:11:59

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'mmHg'	System	29 Sep 2020 16:11:59

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:11:59

FDA-CBER-2022-1614-3338912

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User entered 'mmHg'	System	29 Sep 2020 16:11:59

US3762175
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46

US3762175

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46

US3762175

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:12:39

FDA-CBER-2022-1614-3338916

US3762175

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:12:39

US3762175
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:00

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:13:42

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

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)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:00

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:46
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:13:42

US3762175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:11:32

US3762175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 15:55:16
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:11:32

US3762175
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Home (Home)'	(b) (4), (b) (6)	03 Sep 2020 18:11:32

US3762175
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'VISIT1'	System	03 Sep 2020 18:11:32

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:49:28

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '189730'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:49:28

US3762175
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:00

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:49:28

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

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)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:12:48

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

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)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:12:48

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:12:48

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:12:48

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:12:48

US3762175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:00

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:03
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:13:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:13:54

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Pre-Dose (PREDOSE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:14:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:14:35
User entered 'Yes (Y)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:13:34
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '12:54' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '03 Sep 2020 12:54'	System	29 Sep 2020 16:14:35
User entered empty.	System	29 Sep 2020 16:13:34

FDA-CBER-2022-1614-3338960

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '98.6' F reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '80' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'bpm'	System	29 Sep 2020 16:14:35
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '16' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'breaths/min'	System	29 Sep 2020 16:14:35
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '147' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	29 Sep 2020 16:14:35
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '85' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:14:35
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	29 Sep 2020 16:14:35
User entered empty.	System	29 Sep 2020 16:13:34

US3762175
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:00
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered missing code ND - Not Done.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Post-Dose (POSTDOSE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:18:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 16:18:23
User entered 'Yes (Y)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:18:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 16:13:34
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '14:39' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '03 Sep 2020 14:39'	System	29 Sep 2020 17:46:02
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '98.9' F reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '84' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'bpm'	System	29 Sep 2020 17:46:02
User entered empty.	System	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '12' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'breaths/min'	System	29 Sep 2020 17:46:02
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '147' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	29 Sep 2020 17:46:02
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 17:46:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	29 Sep 2020 17:46:02
User entered '80' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:46:02
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:18:23
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:13:34

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:00
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	29 Sep 2020 17:46:02
User entered empty.	System	29 Sep 2020 16:13:34

US3762175

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:18:34

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:18:34

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:14:45

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:14:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

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)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:14:45

US3762175
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:14:45

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:14:45

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '14:02'	(b) (4), (b) (6)	03 Sep 2020 18:14:45

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '3 Sep 2020 14:02'	System	03 Sep 2020 18:14:45

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:14:45

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'ONCE'	System	03 Sep 2020 18:14:45

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:14:45

US3762175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:15

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:15

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '13:43'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:15

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '03 Sep 2020 13:43'	System	29 Sep 2020 16:19:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '03 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

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Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:00
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '13:44'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '03 Sep 2020 13:44'	System	29 Sep 2020 16:19:37

US3762175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

US3762175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

US3762175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:37

US3762175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered empty.	System	29 Sep 2020 16:19:37

US3762175
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:19:45

FDA-CBER-2022-1614-3339015

US3762175
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	29 Sep 2020 16:19:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:47:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6d68225-5b3d-499c-a7da-5ec35d75bc95'	System	03 Sep 2020 20:48:19
User entered 'Yes (Y)'	System	03 Sep 2020 20:48:19

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:48:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6d68225-5b3d-499c-a7da-5ec35d75bc95'	System	03 Sep 2020 20:48:19
User entered '99.1'	System	03 Sep 2020 20:48:19

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:47:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6d68225-5b3d-499c-a7da-5ec35d75bc95'	System	03 Sep 2020 20:48:19
User entered 'No (N)'	System	03 Sep 2020 20:48:19

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:48:16', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6d68225-5b3d-499c-a7da-5ec35d75bc95'	System	03 Sep 2020 20:48:19
User entered '03 Sep 2020 16:48'	System	03 Sep 2020 20:48:19

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T06:59:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e4fca31-770f-4a6c-958b-37c799a3b92b'	System	04 Sep 2020 10:59:38
User entered 'Yes (Y)'	System	04 Sep 2020 10:59:38

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T06:58:50', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e4fca31-770f-4a6c-958b-37c799a3b92b'	System	04 Sep 2020 10:59:38
User entered '97.1'	System	04 Sep 2020 10:59:38

FDA-CBER-2022-1614-3339026

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T06:58:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e4fca31-770f-4a6c-958b-37c799a3b92b'	System	04 Sep 2020 10:59:38
User entered 'No (N)'	System	04 Sep 2020 10:59:38

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T06:59:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e4fca31-770f-4a6c-958b-37c799a3b92b'	System	04 Sep 2020 10:59:38
User entered '04 Sep 2020 06:59'	System	04 Sep 2020 10:59:38

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 2'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:49:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0d43415d-a2dc-4957-a603-45b5e683c505'	System	05 Sep 2020 15:50:27
User entered 'Yes (Y)'	System	05 Sep 2020 15:50:27

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0d43415d-a2dc-4957-a603-45b5e683c505'	System	05 Sep 2020 15:50:27
User entered '97.9'	System	05 Sep 2020 15:50:27

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:17', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0d43415d-a2dc-4957-a603-45b5e683c505'	System	05 Sep 2020 15:50:27
User entered 'No (N)'	System	05 Sep 2020 15:50:27

FDA-CBER-2022-1614-3339034

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0d43415d-a2dc-4957-a603-45b5e683c505'	System	05 Sep 2020 15:50:27
User entered '05 Sep 2020 11:50'	System	05 Sep 2020 15:50:27

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 3'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:53:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9d914a4-6d25-4198-9a78-bf2183dac01c'	System	06 Sep 2020 01:54:13
User entered 'Yes (Y)'	System	06 Sep 2020 01:54:13

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:53:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9d914a4-6d25-4198-9a78-bf2183dac01c'	System	06 Sep 2020 01:54:13
User entered '97.8'	System	06 Sep 2020 01:54:13

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:53:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9d914a4-6d25-4198-9a78-bf2183dac01c'	System	06 Sep 2020 01:54:13
User entered 'No (N)'	System	06 Sep 2020 01:54:13

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:54:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9d914a4-6d25-4198-9a78-bf2183dac01c'	System	06 Sep 2020 01:54:13
User entered '05 Sep 2020 21:54'	System	06 Sep 2020 01:54:13

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 4'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f11713eb-6031-4e46-9d45-5a0277420b1b'	System	07 Sep 2020 01:43:48
User entered 'Yes (Y)'	System	07 Sep 2020 01:43:48

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f11713eb-6031-4e46-9d45-5a0277420b1b'	System	07 Sep 2020 01:43:48
User entered '98.0'	System	07 Sep 2020 01:43:48

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f11713eb-6031-4e46-9d45-5a0277420b1b'	System	07 Sep 2020 01:43:48
User entered 'No (N)'	System	07 Sep 2020 01:43:48

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:47', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f11713eb-6031-4e46-9d45-5a0277420b1b'	System	07 Sep 2020 01:43:48
User entered '06 Sep 2020 21:43'	System	07 Sep 2020 01:43:48

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 5'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:20:44', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6544916-8cb3-4a2e-bacb-88d20755977f'	System	08 Sep 2020 01:21:05
User entered 'Yes (Y)'	System	08 Sep 2020 01:21:05

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:20:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6544916-8cb3-4a2e-bacb-88d20755977f'	System	08 Sep 2020 01:21:05
User entered '97.5'	System	08 Sep 2020 01:21:05

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:20:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6544916-8cb3-4a2e-bacb-88d20755977f'	System	08 Sep 2020 01:21:05
User entered 'No (N)'	System	08 Sep 2020 01:21:05

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:02', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a6544916-8cb3-4a2e-bacb-88d20755977f'	System	08 Sep 2020 01:21:05
User entered '07 Sep 2020 21:21'	System	08 Sep 2020 01:21:05

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 6'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '1febd393-576a-4775-84dc-de78c13bf0aa'	System	09 Sep 2020 00:57:38
User entered 'Yes (Y)'	System	09 Sep 2020 00:57:38

FDA-CBER-2022-1614-3339060

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '1febd393-576a-4775-84dc-de78c13bf0aa'	System	09 Sep 2020 00:57:38
User entered '97.6'	System	09 Sep 2020 00:57:38

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:29', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '1febd393-576a-4775-84dc-de78c13bf0aa'	System	09 Sep 2020 00:57:38
User entered 'No (N)'	System	09 Sep 2020 00:57:38

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '1febd393-576a-4775-84dc-de78c13bf0aa'	System	09 Sep 2020 00:57:38
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 00:57:38

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 7'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:09', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '772e59cc-2637-40ea-82f7-926e85bdf3ff'	System	10 Sep 2020 01:29:27
User entered 'Yes (Y)'	System	10 Sep 2020 01:29:27

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:16', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '772e59cc-2637-40ea-82f7-926e85bdf3ff'	System	10 Sep 2020 01:29:27
User entered '98.0'	System	10 Sep 2020 01:29:27

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '772e59cc-2637-40ea-82f7-926e85bdf3ff'	System	10 Sep 2020 01:29:27
User entered 'No (N)'	System	10 Sep 2020 01:29:27

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '772e59cc-2637-40ea-82f7-926e85bdf3ff'	System	10 Sep 2020 01:29:27
User entered '09 Sep 2020 21:29'	System	10 Sep 2020 01:29:27

US3762175
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:49:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '01671b5d-f20f-44bb-90aa-4460c49a8def'	System	03 Sep 2020 20:49:55
User entered 'None (1)'	System	03 Sep 2020 20:49:55

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US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:49:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '01671b5d-f20f-44bb-90aa-4460c49a8def'	System	03 Sep 2020 20:49:55
User entered 'No (N)'	System	03 Sep 2020 20:49:55

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:49:33', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '01671b5d-f20f-44bb-90aa-4460c49a8def'	System	03 Sep 2020 20:49:55
User entered 'No (N)'	System	03 Sep 2020 20:49:55

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:49:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '01671b5d-f20f-44bb-90aa-4460c49a8def'	System	03 Sep 2020 20:49:55
User entered 'None (1)'	System	03 Sep 2020 20:49:55

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US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:49:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '01671b5d-f20f-44bb-90aa-4460c49a8def'	System	03 Sep 2020 20:49:55
User entered '03 Sep 2020 16:49'	System	03 Sep 2020 20:49:55

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '341cb5cb-d467-4f5a-86ed-7e1b9c3115fd'	System	04 Sep 2020 11:02:36
User entered 'None (1)'	System	04 Sep 2020 11:02:36

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:00:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '341cb5cb-d467-4f5a-86ed-7e1b9c3115fd'	System	04 Sep 2020 11:02:36
User entered 'No (N)'	System	04 Sep 2020 11:02:36

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:00:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '341cb5cb-d467-4f5a-86ed-7e1b9c3115fd'	System	04 Sep 2020 11:02:36
User entered 'No (N)'	System	04 Sep 2020 11:02:36

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:01:33', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '341cb5cb-d467-4f5a-86ed-7e1b9c3115fd'	System	04 Sep 2020 11:02:36
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 11:02:36

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '341cb5cb-d467-4f5a-86ed-7e1b9c3115fd'	System	04 Sep 2020 11:02:36
User entered '04 Sep 2020 07:02'	System	04 Sep 2020 11:02:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 2'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:31', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '81fbbde6-0850-431c-a269-dc1ebd6e6a4c'	System	06 Sep 2020 01:53:24
User entered 'None (1)'	System	06 Sep 2020 01:53:24

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:34', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '81fbbde6-0850-431c-a269-dc1ebd6e6a4c'	System	06 Sep 2020 01:53:24
User entered 'No (N)'	System	06 Sep 2020 01:53:24

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '81fbbde6-0850-431c-a269-dc1ebd6e6a4c'	System	06 Sep 2020 01:53:24
User entered 'No (N)'	System	06 Sep 2020 01:53:24

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:43', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '81fbbde6-0850-431c-a269-dc1ebd6e6a4c'	System	06 Sep 2020 01:53:24
User entered 'None (1)'	System	06 Sep 2020 01:53:24

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '81fbbde6-0850-431c-a269-dc1ebd6e6a4c'	System	06 Sep 2020 01:53:24
User entered '05 Sep 2020 11:50'	System	06 Sep 2020 01:53:24

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 3'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:54:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9b81187-7c27-4e14-ad2c-a45e72ad5705'	System	06 Sep 2020 01:55:09
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:55:09

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:54:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9b81187-7c27-4e14-ad2c-a45e72ad5705'	System	06 Sep 2020 01:55:09
User entered 'No (N)'	System	06 Sep 2020 01:55:09

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:54:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9b81187-7c27-4e14-ad2c-a45e72ad5705'	System	06 Sep 2020 01:55:09
User entered 'No (N)'	System	06 Sep 2020 01:55:09

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:54:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9b81187-7c27-4e14-ad2c-a45e72ad5705'	System	06 Sep 2020 01:55:09
User entered 'None (1)'	System	06 Sep 2020 01:55:09

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f9b81187-7c27-4e14-ad2c-a45e72ad5705'	System	06 Sep 2020 01:55:09
User entered '05 Sep 2020 21:55'	System	06 Sep 2020 01:55:09

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 4'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c8533d62-65b9-47af-96fc-ed9de820f172'	System	07 Sep 2020 01:44:11
User entered 'None (1)'	System	07 Sep 2020 01:44:11

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:43:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c8533d62-65b9-47af-96fc-ed9de820f172'	System	07 Sep 2020 01:44:11
User entered 'No (N)'	System	07 Sep 2020 01:44:11

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c8533d62-65b9-47af-96fc-ed9de820f172'	System	07 Sep 2020 01:44:11
User entered 'No (N)'	System	07 Sep 2020 01:44:11

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c8533d62-65b9-47af-96fc-ed9de820f172'	System	07 Sep 2020 01:44:11
User entered 'None (1)'	System	07 Sep 2020 01:44:11

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:08', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c8533d62-65b9-47af-96fc-ed9de820f172'	System	07 Sep 2020 01:44:11
User entered '06 Sep 2020 21:44'	System	07 Sep 2020 01:44:11

FDA-CBER-2022-1614-3339110

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 5'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '5d1a3eec-bba9-4e32-b051-272f401f3768'	System	08 Sep 2020 01:21:23
User entered 'None (1)'	System	08 Sep 2020 01:21:23

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '5d1a3eec-bba9-4e32-b051-272f401f3768'	System	08 Sep 2020 01:21:23
User entered 'No (N)'	System	08 Sep 2020 01:21:23

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '5d1a3eec-bba9-4e32-b051-272f401f3768'	System	08 Sep 2020 01:21:23
User entered 'No (N)'	System	08 Sep 2020 01:21:23

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US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '5d1a3eec-bba9-4e32-b051-272f401f3768'	System	08 Sep 2020 01:21:23
User entered 'None (1)'	System	08 Sep 2020 01:21:23

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '5d1a3eec-bba9-4e32-b051-272f401f3768'	System	08 Sep 2020 01:21:23
User entered '07 Sep 2020 21:21'	System	08 Sep 2020 01:21:23

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 6'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c11ac52d-1578-436f-b114-bcc646ac5478'	System	09 Sep 2020 00:58:07
User entered 'None (1)'	System	09 Sep 2020 00:58:07

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c11ac52d-1578-436f-b114-bcc646ac5478'	System	09 Sep 2020 00:58:07
User entered 'No (N)'	System	09 Sep 2020 00:58:07

FDA-CBER-2022-1614-3339123

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c11ac52d-1578-436f-b114-bcc646ac5478'	System	09 Sep 2020 00:58:07
User entered 'No (N)'	System	09 Sep 2020 00:58:07

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:57:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c11ac52d-1578-436f-b114-bcc646ac5478'	System	09 Sep 2020 00:58:07
User entered 'None (1)'	System	09 Sep 2020 00:58:07

FDA-CBER-2022-1614-3339125

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:03', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c11ac52d-1578-436f-b114-bcc646ac5478'	System	09 Sep 2020 00:58:07
User entered '08 Sep 2020 20:58'	System	09 Sep 2020 00:58:07

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 7'	System	03 Sep 2020 18:14:45

FDA-CBER-2022-1614-3339129

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f1d84770-8b66-4cde-844d-f8c91008e85b'	System	10 Sep 2020 01:29:55
User entered 'None (1)'	System	10 Sep 2020 01:29:55

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:34', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f1d84770-8b66-4cde-844d-f8c91008e85b'	System	10 Sep 2020 01:29:55
User entered 'No (N)'	System	10 Sep 2020 01:29:55

US3762175
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f1d84770-8b66-4cde-844d-f8c91008e85b'	System	10 Sep 2020 01:29:55
User entered 'No (N)'	System	10 Sep 2020 01:29:55

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f1d84770-8b66-4cde-844d-f8c91008e85b'	System	10 Sep 2020 01:29:55
User entered 'None (1)'	System	10 Sep 2020 01:29:55

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f1d84770-8b66-4cde-844d-f8c91008e85b'	System	10 Sep 2020 01:29:55
User entered '09 Sep 2020 21:29'	System	10 Sep 2020 01:29:55

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:17', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:27', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'None (0)'	System	03 Sep 2020 20:50:50

FDA-CBER-2022-1614-3339143

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:41', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered 'No (N)'	System	03 Sep 2020 20:50:50

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-03T16:50:45', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e578aea8-dd21-4da1-868b-4937bf8cd98b'	System	03 Sep 2020 20:50:50
User entered '03 Sep 2020 16:50'	System	03 Sep 2020 20:50:50

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:45', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

FDA-CBER-2022-1614-3339151

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:02:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:03:03', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:03:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'None (0)'	System	04 Sep 2020 11:03:22

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:03:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered 'No (N)'	System	04 Sep 2020 11:03:22

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-04T07:03:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'aacaf325-2c3c-40c6-a712-65385f47946b'	System	04 Sep 2020 11:03:22
User entered '04 Sep 2020 07:03'	System	04 Sep 2020 11:03:22

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 2'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:50', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:50:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:51:02', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:51:06', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:51:09', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'None (0)'	System	06 Sep 2020 01:53:25

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:51:13', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered 'No (N)'	System	06 Sep 2020 01:53:25

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T11:51:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3cdbfc59-2344-4ab6-9be7-b93c2429f149'	System	06 Sep 2020 01:53:25
User entered '05 Sep 2020 11:51'	System	06 Sep 2020 01:53:25

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 3'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:15', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'None (0)'	System	06 Sep 2020 01:56:04

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:55:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered 'No (N)'	System	06 Sep 2020 01:56:04

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-05T21:56:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '91c77a20-85c4-4725-9e5a-bd508750d178'	System	06 Sep 2020 01:56:04
User entered '05 Sep 2020 21:56'	System	06 Sep 2020 01:56:04

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

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US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 4'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:12', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:15', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:18', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:27', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'None (0)'	System	07 Sep 2020 01:44:46

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:33', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered 'No (N)'	System	07 Sep 2020 01:44:46

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-06T21:44:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'c7469c44-99d7-4579-954f-ef9f390d1db8'	System	07 Sep 2020 01:44:46
User entered '06 Sep 2020 21:44'	System	07 Sep 2020 01:44:46

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 5'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:28', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:33', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

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US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'None (0)'	System	08 Sep 2020 01:21:56

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered 'No (N)'	System	08 Sep 2020 01:21:56

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-07T21:21:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0a703ca7-f534-4b90-8453-98d3360e992e'	System	08 Sep 2020 01:21:56
User entered '07 Sep 2020 21:21'	System	08 Sep 2020 01:21:56

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US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 6'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:16', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

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US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:23', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'None (0)'	System	09 Sep 2020 00:58:39

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:29', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered 'No (N)'	System	09 Sep 2020 00:58:39

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-08T20:58:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ea5e2282-6728-45ad-b1d1-042a84971a0e'	System	09 Sep 2020 00:58:39
User entered '08 Sep 2020 20:58'	System	09 Sep 2020 00:58:39

FDA-CBER-2022-1614-3339211

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 7'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:29:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

FDA-CBER-2022-1614-3339216

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:02', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

US3762175
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:08', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'None (0)'	System	10 Sep 2020 01:30:23

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:12', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered 'No (N)'	System	10 Sep 2020 01:30:23

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-09-09T21:30:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e9e8a12d-36b6-41cd-ac7e-0ca30abf4340'	System	10 Sep 2020 01:30:23
User entered '09 Sep 2020 21:30'	System	10 Sep 2020 01:30:23

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:14:45

US3762175

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:21:15

US3762175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '10 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:21:15

US3762175
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:21:15

US3762175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:21:15

US3762175

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:25:13

US3762175
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	29 Sep 2020 16:25:13

US3762175
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:26:34

US3762175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '17 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:26:34

US3762175
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:26:34

US3762175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:26:34

US3762175
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:26:52

US3762175
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	29 Sep 2020 16:26:52

US3762175
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:27:35

US3762175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '25 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:27:35

US3762175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:27:35

US3762175
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:27:35

US3762175

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:27:42

US3762175
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	29 Sep 2020 16:27:42

US3762175
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:57:07

US3762175
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Per GCL Lab Reconciliation Requery1:Per response, "Samples received ", however swab data is not updated yet, please verify and update as appropriate.Thanks' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:55:06
User closed query 'Per CDM RQ : Response noted. The Immunogenicity sample is not yet updated. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:59:58
Query 'Per CDM RQ : Response noted. The Immunogenicity sample is not yet updated. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:49
Query 'Per GCL Lab Reconciliation Requery1:Per response, "Samples received ", however swab data is not updated yet, please verify and update as appropriate.Thanks' answered with 'updated' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:43
User opened query 'Per CDM RQ : Response noted. The Immunogenicity sample is not yet updated. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:23:36
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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)	04 Nov 2020 12:23:36
User opened query 'Per GCL Lab Reconciliation Requery1:Per response, "Samples received ", however swab data is not updated yet, please verify and update as appropriate.Thanks' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:05:40

US3762175
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit 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)	04 Nov 2020 07:05:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit 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 'Samples received' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:39:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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 'Samples received ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:39:34
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit 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)	22 Oct 2020 09:18:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit 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 15:29:19
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 15:57:07

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US3762175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:57:07

US3762175
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'VISIT2'	System	01 Oct 2020 15:57:07

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Nov 2020 17:26:28
User entered '11:06' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Nov 2020 17:26:15
User entered '11:66' (non-conformant).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '01 Oct 2020 11:06'	System	09 Nov 2020 17:26:28
User entered '01 Oct 2020 11:66' (non-conformant).	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '98.8' F	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '74'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'bpm'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '16'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:00
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'breaths/min'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '148'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '80'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '12:24'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '01 Oct 2020 12:24'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '98.8' F	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '76'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'bpm'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '12'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'breaths/min'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '163'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '72'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	09 Nov 2020 17:26:15

US3762175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:46

US3762175
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:26:46

US3762175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:00:51

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:00:51

US3762175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

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)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:00:51

FDA-CBER-2022-1614-3339284

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 16:00:51

US3762175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:00:51

US3762175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:00

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '11:45'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:00:51

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1 Oct 2020 11:45'	System	01 Oct 2020 16:00:51

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	28 Oct 2020 14:15:15
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	28 Oct 2020 14:15:15
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 14:15:15
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	01 Oct 2020 16:00:51
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	01 Oct 2020 16:00:51

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'ONCE'	System	01 Oct 2020 16:00:51

US3762175
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:00
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 16:00:51

FDA-CBER-2022-1614-3339291

US3762175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:03

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:03

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:00
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '11:19'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:03

US3762175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '01 Oct 2020 11:19'	System	09 Nov 2020 17:27:03

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '11:22'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '01 Oct 2020 11:22'	System	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:27:24

US3762175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered empty.	System	09 Nov 2020 17:27:24

US3762175
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:56:30

US3762175
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	01 Oct 2020 15:56:30

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:29:19', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a424210-51ce-4426-a105-5713f789eee6'	System	01 Oct 2020 16:29:45
User entered 'Yes (Y)'	System	01 Oct 2020 16:29:45

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:29:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a424210-51ce-4426-a105-5713f789eee6'	System	01 Oct 2020 16:29:45
User entered '98.8'	System	01 Oct 2020 16:29:45

FDA-CBER-2022-1614-3339309

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:29:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a424210-51ce-4426-a105-5713f789eee6'	System	01 Oct 2020 16:29:45
User entered 'No (N)'	System	01 Oct 2020 16:29:45

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:29:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a424210-51ce-4426-a105-5713f789eee6'	System	01 Oct 2020 16:29:45
User entered '01 Oct 2020 12:29'	System	01 Oct 2020 16:29:45

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 12:05'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 14:35'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:13:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b148ce69-7328-460b-b1e8-a152c91be469'	System	02 Oct 2020 04:14:24
User entered 'Yes (Y)'	System	02 Oct 2020 04:14:24

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:14:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b148ce69-7328-460b-b1e8-a152c91be469'	System	02 Oct 2020 04:14:24
User entered '96.5'	System	02 Oct 2020 04:14:24

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US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:14:13', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b148ce69-7328-460b-b1e8-a152c91be469'	System	02 Oct 2020 04:14:24
User entered 'No (N)'	System	02 Oct 2020 04:14:24

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:14:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b148ce69-7328-460b-b1e8-a152c91be469'	System	02 Oct 2020 04:14:24
User entered '02 Oct 2020 00:14'	System	02 Oct 2020 04:14:24

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 15:30'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 2'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:32:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e5905e97-8e27-4021-9569-729427ee61e8'	System	03 Oct 2020 00:33:14
User entered 'Yes (Y)'	System	03 Oct 2020 00:33:14

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:32:33', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e5905e97-8e27-4021-9569-729427ee61e8'	System	03 Oct 2020 00:33:14
User entered '99.2'	System	03 Oct 2020 00:33:14

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:32:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e5905e97-8e27-4021-9569-729427ee61e8'	System	03 Oct 2020 00:33:14
User entered 'No (N)'	System	03 Oct 2020 00:33:14

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:33:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e5905e97-8e27-4021-9569-729427ee61e8'	System	03 Oct 2020 00:33:14
User entered '02 Oct 2020 20:33'	System	03 Oct 2020 00:33:14

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 3'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:25:19', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered 'Yes (Y)'	System	04 Oct 2020 01:26:14

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:25:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered '98.0'	System	04 Oct 2020 01:26:14

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US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:25:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered 'Yes (Y)'	System	04 Oct 2020 01:26:14

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
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)	03 Nov 2020 20:25:06
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 'UPDATED' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:42:32
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 01:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:25:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered '1'	System	04 Oct 2020 01:26:14

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:25:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered '0'	System	04 Oct 2020 01:26:14

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US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:26:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7d101180-b970-43f1-b287-25357fbd8106'	System	04 Oct 2020 01:26:14
User entered '03 Oct 2020 21:26'	System	04 Oct 2020 01:26:14

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 4'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:19', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '02248315-9d83-4543-bd73-ba5d16a1eabf'	System	04 Oct 2020 20:50:38
User entered 'Yes (Y)'	System	04 Oct 2020 20:50:38

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '02248315-9d83-4543-bd73-ba5d16a1eabf'	System	04 Oct 2020 20:50:38
User entered '98.4'	System	04 Oct 2020 20:50:38

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '02248315-9d83-4543-bd73-ba5d16a1eabf'	System	04 Oct 2020 20:50:38
User entered 'No (N)'	System	04 Oct 2020 20:50:38

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '02248315-9d83-4543-bd73-ba5d16a1eabf'	System	04 Oct 2020 20:50:38
User entered '04 Oct 2020 16:50'	System	04 Oct 2020 20:50:38

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 5'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:14:45', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8ca98c63-f84f-4250-b30f-97376f5f65ba'	System	06 Oct 2020 01:15:04
User entered 'Yes (Y)'	System	06 Oct 2020 01:15:04

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:14:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8ca98c63-f84f-4250-b30f-97376f5f65ba'	System	06 Oct 2020 01:15:04
User entered '96.5'	System	06 Oct 2020 01:15:04

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:14:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8ca98c63-f84f-4250-b30f-97376f5f65ba'	System	06 Oct 2020 01:15:04
User entered 'No (N)'	System	06 Oct 2020 01:15:04

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:15:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8ca98c63-f84f-4250-b30f-97376f5f65ba'	System	06 Oct 2020 01:15:04
User entered '05 Oct 2020 21:15'	System	06 Oct 2020 01:15:04

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 6'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:47:53', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '25583e6d-8065-48d0-a5c6-a3950a9aab44'	System	07 Oct 2020 02:48:18
User entered 'Yes (Y)'	System	07 Oct 2020 02:48:18

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '25583e6d-8065-48d0-a5c6-a3950a9aab44'	System	07 Oct 2020 02:48:18
User entered '98.1'	System	07 Oct 2020 02:48:18

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US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '25583e6d-8065-48d0-a5c6-a3950a9aab44'	System	07 Oct 2020 02:48:18
User entered 'No (N)'	System	07 Oct 2020 02:48:18

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '25583e6d-8065-48d0-a5c6-a3950a9aab44'	System	07 Oct 2020 02:48:18
User entered '06 Oct 2020 22:48'	System	07 Oct 2020 02:48:18

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 7'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:16:43', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'caab8349-e792-4ba1-a96b-8182281734e3'	System	08 Oct 2020 03:17:08
User entered 'Yes (Y)'	System	08 Oct 2020 03:17:08

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:16:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'caab8349-e792-4ba1-a96b-8182281734e3'	System	08 Oct 2020 03:17:08
User entered '97.2'	System	08 Oct 2020 03:17:08

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:16:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'caab8349-e792-4ba1-a96b-8182281734e3'	System	08 Oct 2020 03:17:08
User entered 'No (N)'	System	08 Oct 2020 03:17:08

US3762175
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'caab8349-e792-4ba1-a96b-8182281734e3'	System	08 Oct 2020 03:17:08
User entered '07 Oct 2020 23:17'	System	08 Oct 2020 03:17:08

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:30:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4eba138f-77a7-4f3a-b1ca-5a5bc1de4555'	System	01 Oct 2020 16:31:02
User entered 'None (1)'	System	01 Oct 2020 16:31:02

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:30:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4eba138f-77a7-4f3a-b1ca-5a5bc1de4555'	System	01 Oct 2020 16:31:02
User entered 'No (N)'	System	01 Oct 2020 16:31:02

FDA-CBER-2022-1614-3339367

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:30:43', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4eba138f-77a7-4f3a-b1ca-5a5bc1de4555'	System	01 Oct 2020 16:31:02
User entered 'No (N)'	System	01 Oct 2020 16:31:02

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:30:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4eba138f-77a7-4f3a-b1ca-5a5bc1de4555'	System	01 Oct 2020 16:31:02
User entered 'None (1)'	System	01 Oct 2020 16:31:02

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:30:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4eba138f-77a7-4f3a-b1ca-5a5bc1de4555'	System	01 Oct 2020 16:31:02
User entered '01 Oct 2020 12:30'	System	01 Oct 2020 16:31:02

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 12:05'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 14:35'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:15:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7df8749c-90ee-436b-96b0-85cd2b5b53c9'	System	02 Oct 2020 04:16:42
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 04:16:42

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:15:31', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7df8749c-90ee-436b-96b0-85cd2b5b53c9'	System	02 Oct 2020 04:16:42
User entered 'No (N)'	System	02 Oct 2020 04:16:42

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:15:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7df8749c-90ee-436b-96b0-85cd2b5b53c9'	System	02 Oct 2020 04:16:42
User entered 'No (N)'	System	02 Oct 2020 04:16:42

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:16:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7df8749c-90ee-436b-96b0-85cd2b5b53c9'	System	02 Oct 2020 04:16:42
User entered 'None (1)'	System	02 Oct 2020 04:16:42

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:16:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '7df8749c-90ee-436b-96b0-85cd2b5b53c9'	System	02 Oct 2020 04:16:42
User entered '02 Oct 2020 00:16'	System	02 Oct 2020 04:16:42

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 15:30'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 2'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:33:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 00:38:26

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:33:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered 'No (N)'	System	03 Oct 2020 00:38:26

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US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:33:41', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered 'Yes (Y)'	System	03 Oct 2020 00:38:26

FDA-CBER-2022-1614-3339384

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:37:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered '50'	System	03 Oct 2020 00:38:26

FDA-CBER-2022-1614-3339385

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:38:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered 'None (1)'	System	03 Oct 2020 00:38:26

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:38:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '97930654-8467-49b4-8c3b-ed0ca71bb6ac'	System	03 Oct 2020 00:38:26
User entered '02 Oct 2020 20:38'	System	03 Oct 2020 00:38:26

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 3'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:26:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 01:36:55

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:26:29', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered 'Yes (Y)'	System	04 Oct 2020 01:36:55

FDA-CBER-2022-1614-3339392

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:34:34', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered '30'	System	04 Oct 2020 01:36:55

FDA-CBER-2022-1614-3339393

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:34:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered 'Yes (Y)'	System	04 Oct 2020 01:36:55

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:36:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered '130'	System	04 Oct 2020 01:36:55

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:36:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered 'None (1)'	System	04 Oct 2020 01:36:55

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:36:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78610e7a-decd-411e-a2af-9e0dca17a47b'	System	04 Oct 2020 01:36:55
User entered '03 Oct 2020 21:36'	System	04 Oct 2020 01:36:55

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 4'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered 'Does not interfere with activity (2)'	System	04 Oct 2020 20:51:34

FDA-CBER-2022-1614-3339401

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:50:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered 'Yes (Y)'	System	04 Oct 2020 20:51:34

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:06', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered '10'	System	04 Oct 2020 20:51:34

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:10', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered 'Yes (Y)'	System	04 Oct 2020 20:51:34

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered '135'	System	04 Oct 2020 20:51:34

FDA-CBER-2022-1614-3339405

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered 'None (1)'	System	04 Oct 2020 20:51:34

FDA-CBER-2022-1614-3339406

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dd52031e-d1b1-49c3-b46e-24d049a39078'	System	04 Oct 2020 20:51:34
User entered '04 Oct 2020 16:51'	System	04 Oct 2020 20:51:34

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 5'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:15:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered 'None (1)'	System	06 Oct 2020 01:19:36

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:15:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered 'No (N)'	System	06 Oct 2020 01:19:36

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:15:34', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered 'Yes (Y)'	System	06 Oct 2020 01:19:36

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered '110'	System	06 Oct 2020 01:19:36

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:28', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered 'None (1)'	System	06 Oct 2020 01:19:36

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '39ec0450-32dd-4ff3-b0eb-6a192f01b397'	System	06 Oct 2020 01:19:36
User entered '05 Oct 2020 21:19'	System	06 Oct 2020 01:19:36

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US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 6'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 02:48:57

FDA-CBER-2022-1614-3339420

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered 'No (N)'	System	07 Oct 2020 02:48:57

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered 'Yes (Y)'	System	07 Oct 2020 02:48:57

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:43', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered '95'	System	07 Oct 2020 02:48:57

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered 'None (1)'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:48:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'fae99d00-9a6c-4e8a-a596-0845dec453a9'	System	07 Oct 2020 02:48:57
User entered '06 Oct 2020 22:48'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 7'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:13', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered 'None (1)'	System	08 Oct 2020 03:17:48

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:16', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered 'No (N)'	System	08 Oct 2020 03:17:48

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered 'Yes (Y)'	System	08 Oct 2020 03:17:48

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:37', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered '45'	System	08 Oct 2020 03:17:48

FDA-CBER-2022-1614-3339432

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered 'None (1)'	System	08 Oct 2020 03:17:48

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:44', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '52904987-e57e-4dc4-b175-04fd66659d26'	System	08 Oct 2020 03:17:48
User entered '07 Oct 2020 23:17'	System	08 Oct 2020 03:17:48

FDA-CBER-2022-1614-3339434

US3762175
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:00
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:08', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:12', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:16', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:23', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:27', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'None (0)'	System	01 Oct 2020 16:31:46

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered 'No (N)'	System	01 Oct 2020 16:31:46

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-01T12:31:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '13b88140-2103-4e60-a5bb-42d46e166bce'	System	01 Oct 2020 16:31:46
User entered '01 Oct 2020 12:31'	System	01 Oct 2020 16:31:46

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 12:05'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 14:35'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:16:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:16:53', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:08', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

FDA-CBER-2022-1614-3339453

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'None (0)'	System	02 Oct 2020 04:17:29

FDA-CBER-2022-1614-3339454

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:15', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered 'No (N)'	System	02 Oct 2020 04:17:29

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T00:17:26', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '2d3a5653-c01f-4a1a-aea3-e7dc0b474578'	System	02 Oct 2020 04:17:29
User entered '02 Oct 2020 00:17'	System	02 Oct 2020 04:17:29

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '01 Oct 2020 15:30'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 2'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:47:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:48:42

FDA-CBER-2022-1614-3339460

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:47:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'Some interference with activity (2)'	System	03 Oct 2020 00:48:42

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:47:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:48:42

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:48:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'None (0)'	System	03 Oct 2020 00:48:42

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:48:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'None (0)'	System	03 Oct 2020 00:48:42

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:48:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:48:42

FDA-CBER-2022-1614-3339465

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:48:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered 'No (N)'	System	03 Oct 2020 00:48:42

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-02T20:48:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '3938ab43-fa02-45bd-9745-e8a2aa1b2a28'	System	03 Oct 2020 00:48:42
User entered '02 Oct 2020 20:48'	System	03 Oct 2020 00:48:42

FDA-CBER-2022-1614-3339467

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 3'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:31', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'No interference with activity (1)'	System	04 Oct 2020 01:38:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'None (0)'	System	04 Oct 2020 01:38:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'None (0)'	System	04 Oct 2020 01:38:06

FDA-CBER-2022-1614-3339473

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'None (0)'	System	04 Oct 2020 01:38:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'None (0)'	System	04 Oct 2020 01:38:06

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:53', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'None (0)'	System	04 Oct 2020 01:38:06

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:37:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered 'No (N)'	System	04 Oct 2020 01:38:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-03T21:38:02', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '4c64ce79-2ddb-4633-bbfa-6830bd634dba'	System	04 Oct 2020 01:38:06
User entered '03 Oct 2020 21:38'	System	04 Oct 2020 01:38:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 4'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:39', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:43', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'None (0)'	System	04 Oct 2020 20:52:06

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:51:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered 'No (N)'	System	04 Oct 2020 20:52:06

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US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-04T16:52:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '379859d7-a325-485c-912d-232c0fd4110d'	System	04 Oct 2020 20:52:06
User entered '04 Oct 2020 16:52'	System	04 Oct 2020 20:52:06

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 5'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

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US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

FDA-CBER-2022-1614-3339495

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:53', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'None (0)'	System	06 Oct 2020 01:20:08

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:19:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered 'No (N)'	System	06 Oct 2020 01:20:08

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-05T21:20:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '992b32c1-d7b5-479a-b586-02a0c6167b1d'	System	06 Oct 2020 01:20:08
User entered '05 Oct 2020 21:20'	System	06 Oct 2020 01:20:08

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 6'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:17', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'None (0)'	System	07 Oct 2020 02:49:38

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:28', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered 'No (N)'	System	07 Oct 2020 02:49:38

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-06T22:49:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '920f28cd-56ac-4af6-a33f-9677db84489d'	System	07 Oct 2020 02:49:38
User entered '06 Oct 2020 22:49'	System	07 Oct 2020 02:49:38

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	01 Oct 2020 16:00:51
User entered 'Day 7'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:50', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

FDA-CBER-2022-1614-3339516

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:54', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

FDA-CBER-2022-1614-3339517

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:17:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:18:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'None (0)'	System	08 Oct 2020 03:18:09

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:18:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered 'No (N)'	System	08 Oct 2020 03:18:09

US3762175
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-07T23:18:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '93d320a7-5eb8-4392-b06f-0f750a613a99'	System	08 Oct 2020 03:18:09
User entered '07 Oct 2020 23:18'	System	08 Oct 2020 03:18:09

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:00:51

US3762175

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:00:51

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	07 Oct 2020 02:48:57
User entered 'Day 8'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-08T17:16:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8018a524-952f-4e6f-a953-0ec502775dbb'	System	08 Oct 2020 21:17:07
User entered 'Yes (Y)'	System	08 Oct 2020 21:17:07

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00
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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-08T17:16:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8018a524-952f-4e6f-a953-0ec502775dbb'	System	08 Oct 2020 21:17:07
User entered '5'	System	08 Oct 2020 21:17:07

FDA-CBER-2022-1614-3339527

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-08T17:17:05', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '8018a524-952f-4e6f-a953-0ec502775dbb'	System	08 Oct 2020 21:17:07
User entered '08 Oct 2020 17:17'	System	08 Oct 2020 21:17:07

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(8)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(9)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	08 Oct 2020 03:17:48
User entered 'Day 9'	System	08 Oct 2020 03:17:48

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(9)
Generated On: 10 Jun 2021 09:45:00
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-09T18:17:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f75a1923-6249-4985-8fde-8a2a1ef64c40'	System	09 Oct 2020 22:18:02
User entered 'No (N)'	System	09 Oct 2020 22:18:02

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(9)
Generated On: 10 Jun 2021 09:45:00
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-09T18:17:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'f75a1923-6249-4985-8fde-8a2a1ef64c40'	System	09 Oct 2020 22:18:02
User entered '09 Oct 2020 18:17'	System	09 Oct 2020 22:18:02

US3762175

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:17:48

US3762175
Folder: Diary Dose 2 (1)
Form: Swelling_Day(9)
Generated On: 10 Jun 2021 09:45:00
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:17:48

US3762175
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	07 Oct 2020 02:48:57
User entered 'Day 8'	System	07 Oct 2020 02:48:57

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-08T17:17:09', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a15901fe-e184-4ea7-9c26-3b564f33e2d1'	System	08 Oct 2020 21:17:17
User entered 'No (N)'	System	08 Oct 2020 21:17:17

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-08T17:17:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a15901fe-e184-4ea7-9c26-3b564f33e2d1'	System	08 Oct 2020 21:17:17
User entered '08 Oct 2020 17:17'	System	08 Oct 2020 21:17:17

US3762175
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:48:57

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:48:57

US3762175
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	08 Oct 2020 03:17:48
User entered 'Day 9'	System	08 Oct 2020 03:17:48

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-09T18:18:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '094384ad-0a99-4b5c-8252-7082560825f1'	System	09 Oct 2020 22:18:50
User entered 'No (N)'	System	09 Oct 2020 22:18:50

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:45:00

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-10-09T18:18:45', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '094384ad-0a99-4b5c-8252-7082560825f1'	System	09 Oct 2020 22:18:50
User entered '09 Oct 2020 18:18'	System	09 Oct 2020 22:18:50

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:45:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:17:48

US3762175

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:45:00

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:17:48

US3762175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:14:42

FDA-CBER-2022-1614-3339546

US3762175
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Oct 2020 21:15:02
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	22 Oct 2020 21:15:02
User entered '08 Oct 2020' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:02
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Oct 2020 21:14:42
User entered '22 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:14:42

US3762175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:14:42

US3762175
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:14:42

US3762175

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
	(b) (4)	
User entered 'Yes (Y)'	Kaitlyn Van Leuvan	22 Oct 2020 21:15:09
	(b) (4)	

US3762175
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	22 Oct 2020 21:15:09

US3762175
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:31

FDA-CBER-2022-1614-3339552

US3762175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered '15 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:31

US3762175
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:31

FDA-CBER-2022-1614-3339554

US3762175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:31

FDA-CBER-2022-1614-3339555

US3762175
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:15:35

US3762175

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	22 Oct 2020 21:15:35

US3762175
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:16:01

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '22 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:16:01

FDA-CBER-2022-1614-3339559

US3762175
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:16:01

US3762175
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:16:01

US3762175
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:16:22

US3762175
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	22 Oct 2020 21:16:22

US3762175
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:49:37

FDA-CBER-2022-1614-3339564

US3762175
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:49:37

US3762175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:49:37

US3762175
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:00
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'VISIT3'	System	05 Nov 2020 21:49:37

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '11:22'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '05 Nov 2020 11:22'	System	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '98.9' F	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '76'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'bpm'	System	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '15'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'breaths/min'	System	05 Nov 2020 21:50:12

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US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '163'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '67'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered 'mmHg'	System	05 Nov 2020 21:50:12

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00

US3762175
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00

US3762175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:20

US3762175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered empty.	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:50:20

US3762175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:51:26

US3762175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05-Nov-2020. However, test result date is missing in GCL. Please confirm if 05-Nov-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:39:56
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05-Nov-2020. However, test result date is missing in GCL. Please confirm if 05-Nov-2020 is correct date to update in GCL records.' answered with 'CORRECT DATE' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:44:05
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05-Nov-2020. However, test result date is missing in GCL. Please confirm if 05-Nov-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:05:30
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:51:26

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered '11:33'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:51:26

US3762175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '05 Nov 2020 11:33'	System	05 Nov 2020 21:51:26

US3762175
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Feb 2021 23:09:31
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	05 Nov 2020 21:51:32

US3762175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	05 Nov 2020 21:51:32

US3762175
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 64'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-05T11:18:41', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '08a06b57-6b30-4af0-9f7c-0f57df13062d'	System	05 Nov 2020 16:18:59
User entered 'No (N)'	System	05 Nov 2020 16:18:59

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-05T11:18:49', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '08a06b57-6b30-4af0-9f7c-0f57df13062d'	System	05 Nov 2020 16:18:59
User entered 'No (N)'	System	05 Nov 2020 16:18:59

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-05T11:18:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '08a06b57-6b30-4af0-9f7c-0f57df13062d'	System	05 Nov 2020 16:18:59
User entered '05 Nov 2020 11:18:55'	System	05 Nov 2020 16:18:59

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 71'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-11T19:56:12', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b9dceaf9-3157-45df-b93f-3b6f2c46ce77'	System	12 Nov 2020 00:56:30
User entered 'No (N)'	System	12 Nov 2020 00:56:30

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-11T19:56:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b9dceaf9-3157-45df-b93f-3b6f2c46ce77'	System	12 Nov 2020 00:56:30
User entered 'No (N)'	System	12 Nov 2020 00:56:30

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US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-11T19:56:27', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b9dceaf9-3157-45df-b93f-3b6f2c46ce77'	System	12 Nov 2020 00:56:30
User entered '11 Nov 2020 19:56:27'	System	12 Nov 2020 00:56:30

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 18:14:45

FDA-CBER-2022-1614-3339604

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered 'Day 78'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-18T20:22:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '049ed192-f6b1-436d-aa61-d00bd592e990'	System	19 Nov 2020 01:23:06
User entered 'No (N)'	System	19 Nov 2020 01:23:06

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-18T20:22:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '049ed192-f6b1-436d-aa61-d00bd592e990'	System	19 Nov 2020 01:23:06
User entered 'No (N)'	System	19 Nov 2020 01:23:06

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-18T20:23:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '049ed192-f6b1-436d-aa61-d00bd592e990'	System	19 Nov 2020 01:23:06
User entered '18 Nov 2020 20:23:04'	System	19 Nov 2020 01:23:06

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 18:14:45

US3762175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:32:53
Data entry locked.	System	03 Sep 2020 18:14:45
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 18:14:45

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-22T20:43:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '209f63c2-5ac7-4080-8e98-d73e29ffbf11'	System	23 Nov 2020 01:43:44
User entered 'No (N)'	System	23 Nov 2020 01:43:44

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-22T20:43:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '209f63c2-5ac7-4080-8e98-d73e29ffbf11'	System	23 Nov 2020 01:43:44
User entered 'No (N)'	System	23 Nov 2020 01:43:44

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-22T20:43:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '209f63c2-5ac7-4080-8e98-d73e29ffbf11'	System	23 Nov 2020 01:43:44
User entered '22 Nov 2020 20:43:42'	System	23 Nov 2020 01:43:44

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:24:15

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:24:15

FDA-CBER-2022-1614-3339617

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-29T11:26:38', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '72127865-cf5f-4e1a-b0c6-1c2102778515'	System	29 Nov 2020 16:26:51
User entered 'No (N)'	System	29 Nov 2020 16:26:51

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-29T11:26:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '72127865-cf5f-4e1a-b0c6-1c2102778515'	System	29 Nov 2020 16:26:51
User entered 'No (N)'	System	29 Nov 2020 16:26:51

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-11-29T11:26:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '72127865-cf5f-4e1a-b0c6-1c2102778515'	System	29 Nov 2020 16:26:51
User entered '29 Nov 2020 11:26:46'	System	29 Nov 2020 16:26:51

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-05T11:03:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '31a007b5-c4df-4aac-9d50-7082d8d40f6a'	System	05 Dec 2020 16:04:05
User entered 'No (N)'	System	05 Dec 2020 16:04:05

FDA-CBER-2022-1614-3339624

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-05T11:03:59', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '31a007b5-c4df-4aac-9d50-7082d8d40f6a'	System	05 Dec 2020 16:04:05
User entered 'No (N)'	System	05 Dec 2020 16:04:05

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-05T11:04:02', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '31a007b5-c4df-4aac-9d50-7082d8d40f6a'	System	05 Dec 2020 16:04:05
User entered '05 Dec 2020 11:04:02'	System	05 Dec 2020 16:04:05

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-12T18:29:19', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '17c81024-bd1b-40c2-ac6b-ceefb8707b72'	System	12 Dec 2020 23:29:36
User entered 'No (N)'	System	12 Dec 2020 23:29:36

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-12T18:29:30', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '17c81024-bd1b-40c2-ac6b-ceefb8707b72'	System	12 Dec 2020 23:29:36
User entered 'No (N)'	System	12 Dec 2020 23:29:36

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-12T18:29:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '17c81024-bd1b-40c2-ac6b-ceefb8707b72'	System	12 Dec 2020 23:29:36
User entered '12 Dec 2020 18:29:35'	System	12 Dec 2020 23:29:36

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:52:41', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered 'Yes (Y)'	System	19 Dec 2020 06:54:29

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:53:06', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered 'No (N)'	System	19 Dec 2020 06:54:29

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:53:23', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered 'No (N)'	System	19 Dec 2020 06:54:29

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:53:51', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered 'Yes (Y)'	System	19 Dec 2020 06:54:29

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:54:11', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 06:54:29

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-19T01:54:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ba57e8be-45f6-4e1b-b4cd-704c79d8b2db'	System	19 Dec 2020 06:54:29
User entered '19 Dec 2020 01:54:20'	System	19 Dec 2020 06:54:29

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-26T21:32:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '90ac2607-45d5-49b4-9376-7b6be8b93dae'	System	27 Dec 2020 02:32:28
User entered 'No (N)'	System	27 Dec 2020 02:32:28

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-26T21:32:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '90ac2607-45d5-49b4-9376-7b6be8b93dae'	System	27 Dec 2020 02:32:28
User entered 'No (N)'	System	27 Dec 2020 02:32:28

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2020-12-26T21:32:25', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '90ac2607-45d5-49b4-9376-7b6be8b93dae'	System	27 Dec 2020 02:32:28
User entered '26 Dec 2020 21:32:25'	System	27 Dec 2020 02:32:28

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-02T22:55:03', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e4e201af-c6f3-48dd-90f8-8a53f49f8188'	System	03 Jan 2021 03:55:16
User entered 'No (N)'	System	03 Jan 2021 03:55:16

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-02T22:55:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e4e201af-c6f3-48dd-90f8-8a53f49f8188'	System	03 Jan 2021 03:55:16
User entered 'No (N)'	System	03 Jan 2021 03:55:16

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-02T22:55:13', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e4e201af-c6f3-48dd-90f8-8a53f49f8188'	System	03 Jan 2021 03:55:16
User entered '02 Jan 2021 22:55:13'	System	03 Jan 2021 03:55:16

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-09T22:12:14', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '481d7fa6-32d2-4fe7-aad1-0149876a6afe'	System	10 Jan 2021 03:12:27
User entered 'No (N)'	System	10 Jan 2021 03:12:27

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-09T22:12:21', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '481d7fa6-32d2-4fe7-aad1-0149876a6afe'	System	10 Jan 2021 03:12:27
User entered 'No (N)'	System	10 Jan 2021 03:12:27

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-09T22:12:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '481d7fa6-32d2-4fe7-aad1-0149876a6afe'	System	10 Jan 2021 03:12:27
User entered '09 Jan 2021 22:12:24'	System	10 Jan 2021 03:12:27

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-16T16:36:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '24f4f2ed-e5cc-46c3-ae06-94387bc23b7e'	System	16 Jan 2021 21:37:03
User entered 'Yes (Y)'	System	16 Jan 2021 21:37:03

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-16T16:36:36', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '24f4f2ed-e5cc-46c3-ae06-94387bc23b7e'	System	16 Jan 2021 21:37:03
User entered 'No (N)'	System	16 Jan 2021 21:37:03

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-16T16:36:42', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '24f4f2ed-e5cc-46c3-ae06-94387bc23b7e'	System	16 Jan 2021 21:37:03
User entered 'No (N)'	System	16 Jan 2021 21:37:03

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-16T16:36:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '24f4f2ed-e5cc-46c3-ae06-94387bc23b7e'	System	16 Jan 2021 21:37:03
User entered 'No (N)'	System	16 Jan 2021 21:37:03

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-16T16:37:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '24f4f2ed-e5cc-46c3-ae06-94387bc23b7e'	System	16 Jan 2021 21:37:03
User entered '16 Jan 2021 16:37:01'	System	16 Jan 2021 21:37:03

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-25T21:48:24', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'acb8db22-3920-4511-9232-c1ed8f20d41e'	System	26 Jan 2021 02:48:35
User entered 'No (N)'	System	26 Jan 2021 02:48:35

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-25T21:48:28', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'acb8db22-3920-4511-9232-c1ed8f20d41e'	System	26 Jan 2021 02:48:35
User entered 'No (N)'	System	26 Jan 2021 02:48:35

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-25T21:48:32', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'acb8db22-3920-4511-9232-c1ed8f20d41e'	System	26 Jan 2021 02:48:35
User entered '25 Jan 2021 21:48:32'	System	26 Jan 2021 02:48:35

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-31T23:07:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'df8086d2-8f00-4188-8530-2a29a7d84e31'	System	01 Feb 2021 04:08:00
User entered 'No (N)'	System	01 Feb 2021 04:08:00

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-31T23:07:55', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'df8086d2-8f00-4188-8530-2a29a7d84e31'	System	01 Feb 2021 04:08:00
User entered 'No (N)'	System	01 Feb 2021 04:08:00

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-01-31T23:07:58', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'df8086d2-8f00-4188-8530-2a29a7d84e31'	System	01 Feb 2021 04:08:00
User entered '31 Jan 2021 23:07:58'	System	01 Feb 2021 04:08:00

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:23:47', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered 'Yes (Y)'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:23:53', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered 'No (N)'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:24:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered 'No (N)'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:24:22', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered 'Yes (Y)'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Please 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:24:41', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-06T15:24:46', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'e72d5eb1-ba2c-478f-b6a1-6a4e2da331f1'	System	06 Feb 2021 20:25:04
User entered '06 Feb 2021 15:24:46'	System	06 Feb 2021 20:25:04

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-13T20:36:27', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a19d3649-c10c-4339-8d26-b0358577afec'	System	14 Feb 2021 01:36:44
User entered 'No (N)'	System	14 Feb 2021 01:36:44

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-13T20:36:35', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a19d3649-c10c-4339-8d26-b0358577afec'	System	14 Feb 2021 01:36:44
User entered 'No (N)'	System	14 Feb 2021 01:36:44

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-13T20:36:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'a19d3649-c10c-4339-8d26-b0358577afec'	System	14 Feb 2021 01:36:44
User entered '13 Feb 2021 20:36:40'	System	14 Feb 2021 01:36:44

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-21T23:58:01', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b755ad83-c122-460b-8d71-457e05c87b47'	System	22 Feb 2021 04:58:11
User entered 'No (N)'	System	22 Feb 2021 04:58:11

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-21T23:58:03', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b755ad83-c122-460b-8d71-457e05c87b47'	System	22 Feb 2021 04:58:11
User entered 'No (N)'	System	22 Feb 2021 04:58:11

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-21T23:58:07', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'b755ad83-c122-460b-8d71-457e05c87b47'	System	22 Feb 2021 04:58:11
User entered '21 Feb 2021 23:58:07'	System	22 Feb 2021 04:58:11

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US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-28T14:19:48', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '471feb13-0dfa-4f7c-8774-81e958b40499'	System	28 Feb 2021 19:19:59
User entered 'No (N)'	System	28 Feb 2021 19:19:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-28T14:19:52', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '471feb13-0dfa-4f7c-8774-81e958b40499'	System	28 Feb 2021 19:19:59
User entered 'No (N)'	System	28 Feb 2021 19:19:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-02-28T14:19:56', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '471feb13-0dfa-4f7c-8774-81e958b40499'	System	28 Feb 2021 19:19:59
User entered '28 Feb 2021 14:19:56'	System	28 Feb 2021 19:19:59

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-06T18:06:09', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ccc89ece-09fb-487c-8c39-22db7b2da935'	System	06 Mar 2021 23:11:38
User entered 'No (N)'	System	06 Mar 2021 23:11:38

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-06T18:06:17', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ccc89ece-09fb-487c-8c39-22db7b2da935'	System	06 Mar 2021 23:11:38
User entered 'No (N)'	System	06 Mar 2021 23:11:38

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-06T18:06:20', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'ccc89ece-09fb-487c-8c39-22db7b2da935'	System	06 Mar 2021 23:11:38
User entered '06 Mar 2021 18:06:20'	System	06 Mar 2021 23:11:38

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-13T14:12:01-05:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '735241b2-09b7-4e63-b4ed-dc973e031cce'	System	13 Mar 2021 19:12:13
User entered 'No (N)'	System	13 Mar 2021 19:12:13

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-13T14:12:06-05:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '735241b2-09b7-4e63-b4ed-dc973e031cce'	System	13 Mar 2021 19:12:13
User entered 'No (N)'	System	13 Mar 2021 19:12:13

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-13T14:12:09-05:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '735241b2-09b7-4e63-b4ed-dc973e031cce'	System	13 Mar 2021 19:12:13
User entered '13 Mar 2021 14:12:09'	System	13 Mar 2021 19:12:13

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-20T17:14:37-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dad1d96d-b3e6-4b57-a99e-587e44e8e41b'	System	20 Mar 2021 21:14:53
User entered 'No (N)'	System	20 Mar 2021 21:14:53

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-20T17:14:45-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dad1d96d-b3e6-4b57-a99e-587e44e8e41b'	System	20 Mar 2021 21:14:53
User entered 'No (N)'	System	20 Mar 2021 21:14:53

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-20T17:14:48-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'dad1d96d-b3e6-4b57-a99e-587e44e8e41b'	System	20 Mar 2021 21:14:53
User entered '20 Mar 2021 17:14:48'	System	20 Mar 2021 21:14:53

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-27T16:04:17-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a1bbb4a-a3fb-4c20-8140-0f69f2778663'	System	27 Mar 2021 20:04:28
User entered 'No (N)'	System	27 Mar 2021 20:04:28

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-27T16:04:21-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a1bbb4a-a3fb-4c20-8140-0f69f2778663'	System	27 Mar 2021 20:04:28
User entered 'No (N)'	System	27 Mar 2021 20:04:28

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-27T16:04:26-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9a1bbb4a-a3fb-4c20-8140-0f69f2778663'	System	27 Mar 2021 20:04:28
User entered '27 Mar 2021 16:04:26'	System	27 Mar 2021 20:04:28

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-03T10:20:10-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'cce7fad4-f4a3-4934-813b-9258d9c8a72c'	System	03 Apr 2021 14:20:28
User entered 'No (N)'	System	03 Apr 2021 14:20:28

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-03T10:20:14-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'cce7fad4-f4a3-4934-813b-9258d9c8a72c'	System	03 Apr 2021 14:20:28
User entered 'No (N)'	System	03 Apr 2021 14:20:28

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-03T10:20:21-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'cce7fad4-f4a3-4934-813b-9258d9c8a72c'	System	03 Apr 2021 14:20:28
User entered '03 Apr 2021 10:20:21'	System	03 Apr 2021 14:20:28

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-10T23:09:38-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9763d84f-6093-4188-b810-5e6137682aea'	System	11 Apr 2021 03:09:48
User entered 'No (N)'	System	11 Apr 2021 03:09:48

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-10T23:09:42-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9763d84f-6093-4188-b810-5e6137682aea'	System	11 Apr 2021 03:09:48
User entered 'No (N)'	System	11 Apr 2021 03:09:48

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-10T23:09:45-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '9763d84f-6093-4188-b810-5e6137682aea'	System	11 Apr 2021 03:09:48
User entered '10 Apr 2021 23:09:45'	System	11 Apr 2021 03:09:48

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-18T17:35:40-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e88aeb5-be38-4613-bbd5-9b1ca51a0705'	System	18 Apr 2021 21:35:51
User entered 'No (N)'	System	18 Apr 2021 21:35:51

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-18T17:35:44-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e88aeb5-be38-4613-bbd5-9b1ca51a0705'	System	18 Apr 2021 21:35:51
User entered 'No (N)'	System	18 Apr 2021 21:35:51

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-18T17:35:49-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '0e88aeb5-be38-4613-bbd5-9b1ca51a0705'	System	18 Apr 2021 21:35:51
User entered '18 Apr 2021 17:35:49'	System	18 Apr 2021 21:35:51

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-26T17:52:47-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '058e0b02-e2d6-4d78-83d3-e59a24886eb3'	System	26 Apr 2021 21:52:55
User entered 'No (N)'	System	26 Apr 2021 21:52:55

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-26T17:52:49-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '058e0b02-e2d6-4d78-83d3-e59a24886eb3'	System	26 Apr 2021 21:52:55
User entered 'No (N)'	System	26 Apr 2021 21:52:55

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-04-26T17:52:53-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '058e0b02-e2d6-4d78-83d3-e59a24886eb3'	System	26 Apr 2021 21:52:55
User entered '26 Apr 2021 17:52:53'	System	26 Apr 2021 21:52:55

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-05-02T20:26:10-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78d66fba-41aa-4d49-ae4e-4959f1169f3e'	System	03 May 2021 00:26:19
User entered 'No (N)'	System	03 May 2021 00:26:19

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Have you been exposed to someone with 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 (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-05-02T20:26:13-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78d66fba-41aa-4d49-ae4e-4959f1169f3e'	System	03 May 2021 00:26:19
User entered 'No (N)'	System	03 May 2021 00:26:19

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-05-02T20:26:17-04:00', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: '78d66fba-41aa-4d49-ae4e-4959f1169f3e'	System	03 May 2021 00:26:19
User entered '02 May 2021 20:26:17'	System	03 May 2021 00:26:19

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:24:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:24:15

FDA-CBER-2022-1614-3339763

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:24:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:24:15

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US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:24:15

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US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:24:15

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:24:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:24:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:24:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:24:15

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:24:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:45:00
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:24:15

US3762175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:00

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:24:15
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:24:15

US3762175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:00

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 18:35:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-05T18:35:40', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'bd159b11-f21b-4c77-9cef-ce51b631cb48'	System	05 Mar 2021 23:36:08
User entered 'No (N)'	System	05 Mar 2021 23:36:08

US3762175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:00

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:35:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7EB99C07-0491-4678-BAED-999F0F883569)', Time: '2021-03-05T18:36:04', User OID: 'PatientReportedOutcome (US3762175)', ODM File OID: 'bd159b11-f21b-4c77-9cef-ce51b631cb48'	System	05 Mar 2021 23:36:08
User entered '05 Mar 2021 18:36:04'	System	05 Mar 2021 23:36:08

US3762175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 20:44:27

US3762175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:09
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 20:44:27

US3762175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:44:27

US3762175
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:44:27

US3762175

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:33:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:44:33

FDA-CBER-2022-1614-3340006

US3762175
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:31:00
User entered '1'	System	25 Nov 2020 20:44:33

US3762175
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 15:32:03

US3762175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '30 Dec 2020'	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 15:32:03

US3762175
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 15:32:03

US3762175
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 15:32:03

US3762175
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	25 Jan 2021 15:32:07

US3762175
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:00
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:10
User entered '1'	System	25 Jan 2021 15:32:07

US3762175
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	28 Jan 2021 19:51:29

US3762175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '28 Jan 2021'	Samantha Wheeler (b) (4) (b) (4)	28 Jan 2021 19:51:29

US3762175
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Contact Made (CONTACT MADE)'	Samantha Wheeler (b) (4) (b) (4)	28 Jan 2021 19:51:29

US3762175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	28 Jan 2021 19:51:29

US3762175

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	28 Jan 2021 19:51:37

US3762175

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:37:54
User entered '1'	System	28 Jan 2021 19:51:37

US3762175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	10 Mar 2021 14:52:17

US3762175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	10 Mar 2021 14:52:17

US3762175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:00

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	10 Mar 2021 14:52:17

US3762175
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:00
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	10 Mar 2021 14:52:17

US3762175

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	10 Mar 2021 14:53:11

US3762175

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 14:53:11

US3762175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:54:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 14:54:59

US3762175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Apr 2021 14:54:59

US3762175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 14:54:59

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:00

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Pulse units

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:07

US3762175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 14:55:07

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 14:55:19

FDA-CBER-2022-1614-3340045

US3762175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:00

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 14:55:19

US3762175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:55:44

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 14:55:44

US3762175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '10:31'	(b) (4), (b) (6)	09 Apr 2021 14:55:44

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 10:31'	System	09 Apr 2021 14:55:44

US3762175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:55:50

US3762175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:00

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 14:55:50

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:39

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '19 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:39

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:39

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:00

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 22:05:39

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '19 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:31:39

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:31:39

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered '19 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 14:00:45
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 14:00:45
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:24

US3762175
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:45:00
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User entered empty.	System	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:00

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User entered empty.	System	19 Jan 2021 22:05:24

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:06

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '19 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:06

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '10:12'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:05:06

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User entered '19 Jan 2021 10:12'	System	19 Jan 2021 22:05:06

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:00

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:04:51

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '19 Jan 2021'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:04:51

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:00

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '10:14'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 22:04:51

US3762175

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:00

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:30
User entered '19 Jan 2021 10:14'	System	19 Jan 2021 22:04:51

US3762175
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:45:00

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:22
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:53:46
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'The Diary entry for Day 159 is related to a con-procedure and is part of the patients medial history' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:52:39
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 17:11:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26

US3762175
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:45:00

Did the participant experience any adverse events?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of SWELLING/HARDNESS AT INJECTION SITE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 13:40:05
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of SWELLING/HARDNESS AT INJECTION SITE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Ae log updated' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:10:16
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of SWELLING/HARDNESS AT INJECTION SITE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 09:25:01
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:18:07
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:28:46

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:01:58
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'AE REPORTING PER PROTOCOL' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:16:40
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:50:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:32:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:32:37
Data point term sent to Coder	System	29 Sep 2020 16:31:48
User entered 'injection site pain'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '05 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User entered empty.	System	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '05 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User entered empty.	System	29 Sep 2020 16:31:31

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

FDA-CBER-2022-1614-3340090

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:31:31
	(b) (4)	

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'None (NONE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:00
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User entered '0'	System	29 Sep 2020 16:31:31

US3762175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10
User entered '0'	System	29 Sep 2020 16:31:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:10

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 13:08:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 13:08:05
User closed query 'Per DM CLR-RQ: Response noted. However, laterality is not specified. Review and provide laterality (eg, Right axillary lymphadenopathy ipsilateral vaccination site, Right Axillary Lymphadenopathy contralateral injection site, etc). Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:57:52
Data point term sent to Coder	System	03 Dec 2020 21:50:38
Query 'Per DM CLR-RQ: Response noted. However, laterality is not specified. Review and provide laterality (eg, Right axillary lymphadenopathy ipsilateral vaccination site, Right Axillary Lymphadenopathy contralateral injection site, etc). Update entry as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	03 Dec 2020 21:50:22
Coding entries removed.	Samantha Wheeler (b) (4) (b) (4)	03 Dec 2020 21:50:17
User entered 'RIGHT AXILLARY LYMPHADENOPATHY contralateral injection site' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	03 Dec 2020 21:50:17
User opened query 'Per DM CLR-RQ: Response noted. However, laterality is not specified. Review and provide laterality (eg, Right axillary lymphadenopathy ipsilateral vaccination site, Right Axillary Lymphadenopathy contralateral injection site, etc). Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 03:12:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Adverse event

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:02:05
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:40:34
Data point term sent to Coder	System	09 Nov 2020 17:24:31
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'updated ' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:23:53
User entered 'Right AXILLARY LYMPHADENOPATHY' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:23:41
Data point term sent to Coder	System	09 Nov 2020 17:23:30
Coding entries removed.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:23:30
User entered 'Axillary lymphadenopathy' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:23:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Adverse event

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:12:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Axillary pain, LLT: Axillary pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:59:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:59:48
Data point term sent to Coder	System	29 Sep 2020 16:35:52
User entered 'right axillary pain'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '04 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:35:15
User entered '00:00' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:35:15
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:34:53
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User entered '04 Sep 2020 00:00'	System	29 Sep 2020 16:35:15
User entered empty.	System	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4)	29 Sep 2020 16:34:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '05 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:35:15
User entered '23:59' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:35:15
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:34:53
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User entered '05 Sep 2020 23:59'	System	29 Sep 2020 16:35:15
User entered empty.	System	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4)	29 Sep 2020 16:34:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'None (NONE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User entered '0'	System	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11
User entered '0'	System	29 Sep 2020 16:34:53

US3762175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

AEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:04:54
User entered 'USA-US130-2020-mRNA-1273-P301000003'	System	23 Dec 2020 18:04:49
User entered 'New'	(b) (4), (b) (6)	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:05:08
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Patient not assessed for covid ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:08:15
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 16:47:01
User closed query 'Per DM CLR: Please note the start date of this AE is sequential with the end date of AE #3. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 16:51:32
Query 'Per DM CLR: Please note the start date of this AE is sequential with the end date of AE #3. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' answered with 'corrected' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 20:05:49
User opened query 'Per DM CLR: Please note the start date of this AE is sequential with the end date of AE #3. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:43:05
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:32:38

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Adverse event

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Per doctor note etiology unknown' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 22:34:37
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)	30 Dec 2020 14:32:28
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle weakness conditions, PT: Muscular weakness, LLT: Lower extremities weakness of - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:16:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:16:49
Data point term sent to Coder	System	21 Dec 2020 21:53:55
User entered 'Bilateral lower extremity weakness'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	11 Feb 2021 20:05:26
User entered '15 Dec 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	11 Feb 2021 20:05:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '16 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Severity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	22 Dec 2020 19:03:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Dec 2020 19:03:01
	(b) (4)	
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	21 Dec 2020 21:53:27
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '16 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 21:28:16
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'This hospitalization was not related to investigational product. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 20:03:37
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 20:00:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 20:00:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 20:00:42
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 19:47:51
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:53:27
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 20:00:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 20:00:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 20:00:42
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:53:27
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 18:32:46
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 22:36:02
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 22:35:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 22:35:21
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:32:06
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'None (NONE)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

None

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 07:30:37
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'per records we reviewed we did not see any additional medications' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	11 Feb 2021 20:06:07
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:42:55
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Outcome

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Dec 2020 21:53:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:52
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:45:00
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 20:44:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 14:29:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 14:29:38
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:39:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'narrative given by primary ' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:39:42
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 17:39:20

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Narrative

Audit	User	Time (GMT)
User entered '1.)Intrathecal pull is refilled on 14DEC2020 with clonodine, bupivicaine, and morphine. Patient reports weakness following previous refill as well. 2.) Part of spine revealed no cord compression or evidence of transverse myelitis. 3.) Neurologic exam was normal except for his vibration and touch in toes 4.) Weakness attributed to dehydration and presumably new pump medication' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 17:39:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:32:14
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 14:31:55
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'Patient was hospitalized for a fall and c/o bilateral lower extremity weakness. He had recently received refill of pain medicine for intrathecal pump and reports similar weakness with prior refill. MRI showed no compression or inflammation. Neuro exam was normal. Patient noted to be dehydrated potentially contributing to weakness. No suggestion that this event was related to study product or procedure. ' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 20:02:51
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Dec 2020 19:03:01
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 19:03:01
User entered '0'	System	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 21:53:27

US3762175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 21:53:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Swelling of injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 17:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 17:13:01
Data point term sent to Coder	System	25 Feb 2021 17:11:41
User entered 'Swelling at injection site'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 14:38:57
Query 'Data is required. Please provide.' answered with 'no time reported by patient ' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 17:11:18
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 17:11:13
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
User entered empty.	System	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered '8 Oct 2020'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 14:38:59
Query 'Data is required. Please provide.' answered with 'no time reported by patient ' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 17:11:22
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 17:11:13
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
User entered empty.	System	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 21:36:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	25 Feb 2021 21:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:11:13
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 21:36:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	25 Feb 2021 21:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:11:13
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 21:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 21:36:06
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	25 Feb 2021 21:36:06
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:11:13
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4), (b) (4)	23 Mar 2021 17:31:26
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

US3762175
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:45:00
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered '0'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:31:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:35
User signature succeeded.	John Sanders (b) (4) (b) (4)	23 Mar 2021 17:31:26
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
User entered '0'	System	25 Feb 2021 17:11:13

US3762175

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15
User entered '0'	System	25 Feb 2021 17:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:45:00

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:43:15

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:45:00

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:22
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User closed query 'Per CDM: In Diary Dose 2 (1)-Temperature Day 3, Medication was taken by the subject to Treat/Prevent pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:09:12
Query 'Per CDM: In Diary Dose 2 (1)-Temperature Day 3, Medication was taken by the subject to Treat/Prevent pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile.' answered with 'updated conmed' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 17:28:18
User opened query 'Per CDM: In Diary Dose 2 (1)-Temperature Day 3, Medication was taken by the subject to Treat/Prevent pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:24:55
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:35:30

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:24:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:24:49
Data point term sent to Coder	System	29 Sep 2020 16:36:57
User entered 'gabapentin'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'PVD'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

FDA-CBER-2022-1614-3340229

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '300'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'three times daily (TID)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4)	29 Sep 2020 16:36:57
	(b) (4)	

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 19:23:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:23:17
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 19:23:17
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:23:17
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User entered '3'	System	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User entered '1'	System	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:33
User entered '804 (804)'	System	29 Sep 2020 16:36:57

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:31:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:31:46
Data point term sent to Coder	System	03 Dec 2020 20:31:05
Coding entries removed.	(b) (4), (b) (6)	03 Dec 2020 20:30:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:08:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:08:37
Data point term sent to Coder	System	29 Sep 2020 16:39:01
User entered 'omeprazole'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:02:01
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'UPDATED MH' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:31:05
User entered 'GASTRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:30:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:56:13
User entered 'h/o gastritis'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '20'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2016'	James Lovette (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

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US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2020'	James Lovette (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User entered '1'	System	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User entered '1'	System	29 Sep 2020 16:38:16

FDA-CBER-2022-1614-3340261

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:34
User entered '804 (804)'	System	29 Sep 2020 16:38:16

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CILOSTAZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:46:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:46:40
Data point term sent to Coder	System	29 Sep 2020 16:40:02
User entered 'cilostazol'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'PVD'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '100'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'twice daily (BID)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:39:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 16:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 16:42:36
Data point term sent to Coder	System	29 Sep 2020 16:41:07
User entered 'simvostatin'	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'high cholesterol'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '20'	James Lovette (b) (4)	29 Sep 2020 16:40:27

FDA-CBER-2022-1614-3340284

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 1988'	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4)	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User entered '1'	System	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User entered '1'	System	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:54:36
User entered '804 (804)'	System	29 Sep 2020 16:40:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DESVENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:43:42
Data point term sent to Coder	System	29 Sep 2020 16:42:10
User entered 'desvenlafaxine'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'depression'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '50'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:41:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:33:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:33:47
Data point term sent to Coder	System	03 Dec 2020 20:33:06
Coding entries removed.	(b) (4), (b) (6)	03 Dec 2020 20:32:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:11:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:11:39
Data point term sent to Coder	System	29 Sep 2020 16:43:14
User entered 'pantoprazole'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:02:14
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'UPDATED IN MH' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:32:31
User entered 'GASTRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:32:17
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:56:50
User entered 'h/o gastritis'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '20'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:42:19

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:35:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:35:49
Data point term sent to Coder	System	03 Dec 2020 20:35:08
Coding entries removed.	(b) (4), (b) (6)	03 Dec 2020 20:34:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:44:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:44:49
Data point term sent to Coder	System	29 Sep 2020 16:44:16
User entered 'furosemide'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

FDA-CBER-2022-1614-3340335

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Per DM CLR: Please specify the location of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:08:04
Query 'Per DM CLR: Please specify the location of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'PER PATIENT TAKES THIS MED FOR LEG EDEMA' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:35:39
User entered 'EDEMA LEGS' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:34:54
User opened query 'Per DM CLR: Please specify the location of EDEMA. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:57:00
User entered 'edema'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '40'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

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EAB) (1725)

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:43:28

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User closed query 'Per DM CLR: Con Med PROVASTATIN was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:48:35
Query 'Per DM CLR: Con Med PROVASTATIN was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'start date was recorded wrong- patient was taking pravastatin prior to study start' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:19:38
User opened query 'Per DM CLR: Con Med PROVASTATIN was added/changed on 01 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:21:27
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:44:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:44:50
Data point term sent to Coder	System	29 Sep 2020 16:44:17

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User entered 'provastatin'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'high cholesterol'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '40'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4)	29 Sep 2020 16:44:13
	(b) (4)	

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:19:20
User entered 'un UNK 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:19:20
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 Sep 2020'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Jan 2021 16:45:46
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '18 Dec 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Jan 2021 16:45:46
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:44:13

FDA-CBER-2022-1614-3340368

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User entered '1'	System	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User entered '1'	System	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:12:40
User entered '804 (804)'	System	29 Sep 2020 16:44:13

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:50:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:50:39
Data point term sent to Coder	System	29 Sep 2020 16:49:27
User entered 'amlodipine'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'high blood pressure'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '5'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

FDA-CBER-2022-1614-3340380

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 UNK 2016'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:48:27

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TRIAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:52:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:52:37
Data point term sent to Coder	System	29 Sep 2020 16:52:36
User entered 'triazolam'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'depression'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '.25'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '01 Sep 2000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:51:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:51:52

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:59:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 16:59:41
Data point term sent to Coder	System	29 Sep 2020 16:58:47
User entered 'vitamin E'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'supplement'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '400'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'ug (ug)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

FDA-CBER-2022-1614-3340413

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:58:26

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:00:44
Data point term sent to Coder	System	29 Sep 2020 16:59:48
User entered 'vitamin d3'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'supplement'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '5000'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'ug (ug)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

FDA-CBER-2022-1614-3340431

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 16:59:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS, PRODUCTSYNONYM: OMEGA 3 6 9 [OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:02:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:02:34
Data point term sent to Coder	System	29 Sep 2020 17:01:51
User entered 'Omega 3-6-9'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

FDA-CBER-2022-1614-3340444

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'supplement'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'tablet (TABLET)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:09:26
User entered 'Yes (Y)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:00:50
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

FDA-CBER-2022-1614-3340456

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 17:09:26
User entered 'No (N)' reason for change: Data Entry Error	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 17:00:50
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:00:50

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VITEX AGNUS-CASTUS EXTRACT, PRODUCTSYNONYM: LUTENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 08:13:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 08:13:38
Data point term sent to Coder	System	29 Sep 2020 17:02:52
User entered 'lutene'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'eye health'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'capsule (CAPSULE)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

FDA-CBER-2022-1614-3340472

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:01:55

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:01:55

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:09:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:09:38
Data point term sent to Coder	System	29 Sep 2020 17:09:03
User entered 'vitamin b12'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'supplement'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '1000' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:32:08
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:01:21
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:55:30
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:55:24
User entered '400' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:55:24
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:56:02
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:02:51
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UPDATED MED SHEET' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:39:24
User entered '400 MG' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:38:49
User entered '1000 MG' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:38:16
User entered '1000MG' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:37:34

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:57:14
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:48:55
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:32:13
User entered 'ug (ug)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	26 Mar 2021 20:32:08
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:45:28
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:55:24
User entered 'mg (mg)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 20:55:24
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'tablet (TABLET)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

FDA-CBER-2022-1614-3340494

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:08:04

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 18:56:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 18:56:48
Data point term sent to Coder	System	03 Dec 2020 20:41:19
Coding entries removed.	(b) (4), (b) (6)	03 Dec 2020 20:40:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:09:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 17:09:38
Data point term sent to Coder	System	29 Sep 2020 17:09:04
User entered 'aspirin'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:04:06
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:40:49
User entered 'PVD' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:40:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:57:59
User entered 'blood thinner'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '81'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

FDA-CBER-2022-1614-3340503

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 17:09:00

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:17:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:17:01
Data point term sent to Coder	System	22 Jan 2021 17:16:11
User entered 'Cyclobenzaprine'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'chronic back pain'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '10'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'UN Aug 2019'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 17:15:24

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Jan 2021 17:15:24

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:54:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:54:57
Data point term sent to Coder	System	22 Jan 2021 17:22:17
User entered 'morphine sulfate'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'chronic back pain'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0.6498'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'daily'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'intrathecal'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'UN UNK 1999'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:22:10

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:27:04
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 Jan 2021 18:27:04
Data point term sent to Coder	System	22 Jan 2021 17:24:19
User entered 'Clonodine'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'chronic back pain'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '26.09'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'ug (ug)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'daily'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'intrathecal'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'UN UNK 1999'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:23:36

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE HYDROCHLORIDE, PRODUCTSYNONYM: BUPIVICAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:52:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:52:03
Data point term sent to Coder	System	22 Jan 2021 17:25:22
User entered 'Bupivicaine'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'chronic back pain'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1.1'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'daily'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'intrathecal'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'UN UNK 1999'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:24:40

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 14:13:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 14:13:44
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
Data point term sent to Coder	System	22 Jan 2021 17:26:25
User entered 'Tumeric root extract'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'osteoarthritis'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '1'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'UN UNK 2016'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:32:49
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Jan 2021 17:25:32

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:25:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 19:25:54
Data point term sent to Coder	System	09 Apr 2021 19:25:19
User entered 'GABAPENTIN'	(b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'PVD'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered '300'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:57:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:00

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 19:24:37

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 19:24:37

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:45:00

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:22
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:49:28

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:16:31
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 16:50:38

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:00

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'CENTRAL NERVOUS SYSTEM INPLANT / pvd' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:21:29
User entered 'CENTRAL NERVOUS SYSTEM INPLANT / CVD' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:20:29
User entered 'Central Nervous System Inplant'	(b) (4), (b) (6)	08 Feb 2021 16:50:38

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:48:47
Query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:22:27
User opened query 'Per DM CLR: Please review the indication = DIAGNOSTIC as the recorded procedure is therapeutic in nature and not being done for diagnostic purposes. Please confirm if procedure is done for a MedHistory or AE condition and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 09:13:52
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	08 Feb 2021 16:50:38

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:00

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 16:50:38

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:00

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:34
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:18:06

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:00

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:34
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:01
User entered '"NEVRO" - PERMANENT WIRES / pvd' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:21:47
User entered '"NEVRO" - PERMANENT WIRES / CVD' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:20:49
User entered '"Nevro" - permanent wires for CNS'	(b) (4), (b) (6)	09 Apr 2021 19:18:06

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:00

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:34
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:18:06

US3762175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:00

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:27:34
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:55:46
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:01
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 19:18:06

FDA-CBER-2022-1614-3340633

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340646

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340655

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340658

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340659

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:59
User entered '23/Dec/2020 18:05'	System	23 Dec 2020 18:05:21

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:00

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.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340676

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340678

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:19:59
User entered '23/Dec/2020 21:16'	System	23 Dec 2020 21:17:01

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:00

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.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 18:32:58
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 21:17:01

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340695

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:45:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '20/Jan/2021 13:33'	System	20 Jan 2021 18:33:15

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:00

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 14:29:50
User entered '1'	(b) (4), (b) (6)	20 Jan 2021 18:33:15

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340710

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340712

Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340713

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340714

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340715

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340716

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:45:00

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
User entered '25/Jan/2021 14:30'	System	25 Jan 2021 14:30:03

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:45:00

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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:48
User entered '1'	(b) (4), (b) (6)	25 Jan 2021 14:30:03

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4) (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'USA-US130-2020-MRNA-1273-P301000003'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Death

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Yes (Y)'	System	23 Dec 2020 18:04:49

US3762175

Folder: SAE USA-US130-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:00

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'No (N)'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340729

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'John'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Sanders'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '100 Medical Center Blvd'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'Winston-Salem'	System	23 Dec 2020 18:04:49

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered 'NC'	System	23 Dec 2020 18:04:49

FDA-CBER-2022-1614-3340734

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 18:05:14
User entered '27157'	System	23 Dec 2020 18:04:49

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:56
Un-reviewed for Safety.	(b) (4), (b) (6)	12 Feb 2021 13:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 15:19:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 21:16:49
User entered 'US'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:00
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	12 Feb 2021 13:59:14
User entered '4'	System	25 Jan 2021 14:30:03
User entered '3'	System	20 Jan 2021 18:33:15
User entered '2'	System	23 Dec 2020 21:17:01
User entered '1'	System	23 Dec 2020 18:05:21

US3762175
Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:45:00
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
User entered '12/Feb/2021 08:59'	(b) (4) System	12 Feb 2021 13:59:14

Folder: SAE USA-US130-2020-MRNA-1273-P301000003
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:45:00
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)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:37:32
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 13:59:14