

US3862110 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:04:33

All time stamps listed in this document are displayed in GMT

US3862110

Form: Participant Creation

Data signed: (b) (4) **02 Apr 2021 14:21:56**

Generated On: 10 Jun 2021 10:04:33

[Participant ID](#)

US3862110

[mRNA-1273-P301 Completion Guidelines](#)

US3862110

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:43:21

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Date of Informed Consent (<i>dd MMM yyyy</i>)	2 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:43:21

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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) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	KERATOCONUS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	BLIND LEFT EYE
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (7)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (8)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	SENSORY NEUROPATHY IN BOTH FEET
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	DRY SKIN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	HUMAN IMMUNODEFICIENCY VIRUS
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	TRANSURETHRAL RESECTION OF THE PROSTATE
Start date (dd MMM yyyy)	UN MAR 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAR 2010
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	MAR 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	DRUG ALLERGY: BACTRIM (RASH)
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	DRUG ALLERGY: HYDROCODONE (ITCH)
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:42
Height (xxx.x)	70.0 in
Weight (xxx.x)	229.0 lb
BMI (xxx.x)	32.92678 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	072 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	092 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☒ No ☐

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:43:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145531

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) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

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) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:42
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	072 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	092 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	12:27 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:27
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 11:57 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 11:57

Which arm was used to give treatment? Left Arm ☐
Right Arm ☒

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	11:32 (24 HR)
Collection date and time (derived)	2 SEP 2020 11:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	2 SEP 2020 11:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

02 SEP 2020 12:29

PC Open Date & Time

02 SEP 2020 12:17

PC Close Date & Time

02 SEP 2020 14:47

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 97.6 °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	02 SEP 2020 18:43
PC Open Date & Time	02 SEP 2020 15:42
PC Close Date & Time	03 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

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

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:26

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:28

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:38

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

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

97.8 °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

06 SEP 2020 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:49

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 SEP 2020 12:30

PC Open Date & Time

02 SEP 2020 12:17

PC Close Date & Time

02 SEP 2020 14:47

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 SEP 2020 18:43

PC Open Date & Time

02 SEP 2020 15:42

PC Close Date & Time

03 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 13:26

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

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.**

None ☒

Please select one response below

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 20:29

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 20:38

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 12:03

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 15:49

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 12:30

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 12:31
PC Open Date & Time	02 SEP 2020 12:17
PC Close Date & Time	02 SEP 2020 14:47

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:42
PC Open Date & Time	02 SEP 2020 15:42
PC Close Date & Time	03 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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EAB) (1725)

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:26
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

61 of 2860

EAB) (1725)

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:30
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

63 of 2860

EAB) (1725)

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:39
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

65 of 2860

EAB) (1725)

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

67 of 2860

EAB) (1725)

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:50
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 ☒

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3862110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	10:02 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:02
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	067 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	092 mmHg
Diastolic Blood Pressure units	MMHG

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:50
Temperature (xxx.x)	097.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	020 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	094 mmHg
Diastolic Blood Pressure units	MMHG

US3862110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 11:20

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

US3862110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	30 SEP 2020
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Collection time (00:00-23:59)	10:50 (24 HR)
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Collection date and time (derived)	30 SEP 2020 10:50
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US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	10:36	30 SEP 2020 10:36

US3862110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 11:40

PC Open Date & Time

30 SEP 2020 11:40

PC Close Date & Time

30 SEP 2020 14:10

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 97.6 °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	30 SEP 2020 23:53
PC Open Date & Time	30 SEP 2020 15:05
PC Close Date & Time	01 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

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

97.5 °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

01 OCT 2020 16:48

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 14:46

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 21:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

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

05 OCT 2020 18:59

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

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

97.6 °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

06 OCT 2020 16:56

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 11:41

PC Open Date & Time

30 SEP 2020 11:40

PC Close Date & Time

30 SEP 2020 14:10

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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

30 SEP 2020 23:54

PC Open Date & Time

30 SEP 2020 15:05

PC Close Date & Time

01 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

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.**

None ☒

Please select one response below

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 16:49

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 14:46

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☐

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

Measure the largest size across any injection site redness with the
ruler provided.

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

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

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 21:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 19:00

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 16:56

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 11:41
PC Open Date & Time	30 SEP 2020 11:40
PC Close Date & Time	30 SEP 2020 14:10

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 23:54
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PC Open Date & Time	30 SEP 2020 15:05
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PC Close Date & Time	01 OCT 2020 11:59
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US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 16:50
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:46
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:13
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 ☒

PRODUCTION RELEASE (v12.003

115 of 2860

EAB) (1725)

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 16:57
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3862110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:21

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:10
Temperature (xxx.x)	098.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	082 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3862110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	10:29 (24 HR)
Collection date and time (derived)	28 OCT 2020 10:29

US3862110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:43:22

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

27 NOV 2020 06:37:24

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 22:34:15
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

11 DEC 2020 11:28:45

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 18:02:21

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 01:36:09

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 01:41:58
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 05:34:19
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 01:11:22

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 05:30:16
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 JAN 2021 19:04:03
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 11:59:10

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

12 FEB 2021 07:04:21

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

22 FEB 2021 09:27:12

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

26 FEB 2021 21:51:57

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 MAR 2021 14:55:01
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

15 MAR 2021 01:21:47

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

21 MAR 2021 16:01:20

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with 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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 APR 2021 22:02:08
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

09 APR 2021 08:05:43

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

17 APR 2021 20:03:44

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

23 APR 2021 07:27:12

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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

30 APR 2021 00:01:44

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 \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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 \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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with 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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
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US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 \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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 \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 ☐

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with 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 <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3862110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:04:33

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		07 MAR 2021 14:55:23

US3862110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:29:45

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:29:45

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

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 _____

US3862110

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:34:59

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	05 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 18:34:59

Generated On: 10 Jun 2021 10:04:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 APR 2021
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 10:22
Temperature (xxx.x)	097.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:34:59

Generated On: 10 Jun 2021 10:04:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3862110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 18:34:58

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	05 APR 2021
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Collection time (00:00-23:59)	10:43 (24 HR)
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Collection date and time (derived)	05 APR 2021 10:43
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US3862110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:34:58

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:54:12

Generated On: 10 Jun 2021 10:04:33

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 APR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862110

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:54:12

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862110

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862110

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☐

US3862110

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	22 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3862110

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Date of updated informed consent (dd MMM yyyy) 22 FEB 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) 22 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3862110

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 FEB 2021
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Collection time (00:00-23:59)	10:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 FEB 2021 10:30
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US3862110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	22 FEB 2021
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Collection time (00:00 - 23:59)	10:27
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Collection Date and Time (derived)	22 FEB 2021 10:27
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US3862110

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:16:01

Generated On: 10 Jun 2021 10:04:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

AEID

Adverse event

MOSQUITO BITES ON
BILATERAL ARMS AND LEGS

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)

24 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

PRODUCTION RELEASE (v12.003

342 of 2860

EAB) (1725)

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	FATTY LIVER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	UNCONTROLLED OBESITY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	COLON POLYP
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

AEID

Adverse event

UNCONTROLLED
HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	VOMITING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	MILD INTERMITTENT STUTTERING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

AEID	USA-US121-2021-MRNA-1273-P30 1000007
Adverse event	CEREBROVASCULAR ACCIDENT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	31 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	LEFT SIDED HEMIPARESIS
Narrative	

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

60 YEARS OLD AFRICAN
AMERICAN MALE
MEDICAL HISTORY: HTN, TYPE
2 DM, OBESITY,
HYPERLIPIDEMIA, HIV
INFECTION, BPH, ANXIETY,
GERD, SEASONAL ALLERGIES,
NEUROPATHY,
MEDICATIONS: FARXIGA,
TOPAMAX, PHENTERMINE,
CONTRAVE, NEXIUM, DOVATO,
LORATADINE, REPATHA,
GABAPENTIN, BUMETANIDE,
DILTIAZEM, LISINAPRIL,
MYRBETRIQ, ASPIRIN
EUA UNBLINDING: 22 FEB 2021
RANDOMIZED TREATMENT
ARM: MRNA 1273
FIRST DOSE: 02 SEP 2020
SECOND DOSE: 30 SEP 2020
SUBJECT CAME IN 05 APR 2021
FOR SCHEDULED VISIT 4 AND
REPORTED THE FOLLOWING:
1. 29 MAR 2021: CURRENT MILD
STUTTERING (PREVIOUSLY
REPORTED AE # 10) BECAME
PROGRESSIVELY WORST WITH
“WEAKNESS”, “NUMBNESS” OF
LEFT ARM AND LEFT LEG. WIFE
NOTICED LEFT FACIAL DROOP.
WENT TO ER AND WAS
ADMITTED ON THE SAME DAY.
HAD CT SCAN AND MRI OF
BRAIN: “NO BLEEDING, NO
BLOOD CLOT”.
SUBJECT WAS TOLD HE HAD A
“STROKE”.

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

2. 31 MAR 2021: DISCHARGED
HOME, PRESCRIBED WITH
ASPIRIN 81 MG. WILL
UNDERGO HOME SPEECH,
PHYSICAL, OCCUPATIONAL
THERAPY
SUBJECT WITH PRONOUNCED
STUTTERING, RESIDUAL LEFT
SIDED WEAKNESS AND
LIMPING ON AMBULATION.
WILL REQUEST MEDICAL
RECORDS FOR DETAILS.

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

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

AEID	
Adverse event	LEFT SIDED HEMIPARESIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

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Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

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

Yes ☒

No ☐

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

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication FARXIGA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication TRULICITY

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 1.5/.5

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify MG/ML

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 (2)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 0.1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☒
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21	OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input checked="" type="radio"/>
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication MYBETRIQ

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication AMMONIA LACTATE 12%

Prophylaxis Yes ☐
No ☒

Indication DRY SKIN

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication TOPAMAX

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication PHENTERMINE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 37.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication DRISDOL

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 1.25

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication DOVATO

Prophylaxis Yes ☐
No ☒

Indication HUMAN IMMUNODEFICIENCY
VIRUS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication REPATHA

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 140

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

EVERY TWO WEEKS

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) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication SENSORY NEUROPATHY IN BOTH FEET

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication NEOSPORIN OINTMENT
(BACITRACIN 400 UNITS
,NEOMYCIN 3.5 MG,
POLYMYXIN B 5,000 UNITS PER
1 GRAM)

Prophylaxis Yes ☐
No ☒

Indication MOSQUITO BITES ON
BILATERAL ARMS AND LEGS

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 18:34:55

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	Topical	<input checked="" type="radio"/>
	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	3 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication INFLUENZA VACCINE HIGH DOSE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication DILTIAZEM ER

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 240

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED
HYPERTENSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication CONTRAVE
(NALTREXONE 8 MG
BUPROPION HCL 90 MG)

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED OBESITY

Dose per administration 8/90

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication CONTRAVE
(NALTREXONE 8 MG
BUPROPION HCL 90 MG)

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED OBESITY

Dose per administration 8/90

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED
HYPERTENSION

Dose per administration

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication CONTRAVE
(NALTREXONE 8MG
BUPROPION HCL 90 MG)

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED OBESITY

Dose per administration 8/90

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

2 TABLETS IN AM
1 TABLET IN PM

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication CONTRAVE
(NALTREXONE 8 MG
BUPROPION 90 MG)

Prophylaxis Yes ☐
No ☒

Indication UNCONTROLLED
OBESITY

Dose per administration 8/90

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

2 TABLETS TWO TIMES A DAY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication APPLE CIDER GUMMIES

Prophylaxis Yes ☒
No ☐

Indication GENERAL WELL BEING

Dose per administration 1200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST VACCINATION
REACTOGENICITY SYMPTOM:
HEADACHE

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 ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication THROMBOEMBOLITIC STROKE
PREVENTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 09 Apr 2021 18:34:55

Generated On: 10 Jun 2021 10:04:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 14:21:57

Generated On: 10 Jun 2021 10:04:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 NOV 2020	CT SCAN OF ABDOMEN AND PELVIS	Adverse Event	
30 NOV 2020	COLONOSCOPY	Adverse Event	

US3862110

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:04:33

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

US3862110

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:04:33

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 ☐

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 14:01:04

Generated On: 10 Jun 2021 10:04:33

SAEID	USA-US121-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 14:01:04

Generated On: 10 Jun 2021 10:04:33

SAEID	USA-US121-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 10:06
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

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 14:01:04

Generated On: 10 Jun 2021 10:04:33

SAEID	USA-US121-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 12:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 14:01:04

Generated On: 10 Jun 2021 10:04:33

SAEID	USA-US121-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 07:54
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

US3862110 (Prod: Baylor College of Medicine)

US3862110

Form: Participant Creation

Generated On: 10 Jun 2021 10:04:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'US3862110'	RWS_ENDPOINT	02 Sep 2020 16:05:43
	ENDPOINT (b) (4)	
	(b) (4)	

US3862110

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 14:00:34

US3862110

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:44

US3862110

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Clinic (Clinic)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:00:34

US3862110

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'SCRN'	System	03 Sep 2020 14:00:34

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:45

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '60'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'YEARS'	System	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '60'	System	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Male (M)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'I'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:10:43

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Sep 2020'	System	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2020'	System	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Amendment 3 (3)'	Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:04

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:05:44

US3862110

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'I'	System	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:04:33

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:04:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:12:01

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Corneal structural change, deposit and degeneration, PT: Keratoconus, LLT: Keratoconus - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:25:46
Data point term sent to Coder	System	03 Sep 2020 16:24:47
User entered 'keratoconus'	Trent Davis (b) (4)	03 Sep 2020 16:23:53
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1980'	Trent Davis (b) (4)	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1980'	System	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1980'	System	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:23:53

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:25:46
Data point term sent to Coder	System	03 Sep 2020 16:24:47
User entered 'Hypertension'	Trent Davis (b) (4)	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1995' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:03:02
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:24:08
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:03:02
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 16:24:08
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1995'	System	28 Oct 2020 16:03:02
User entered empty.	System	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1995'	System	28 Oct 2020 16:03:02
User entered empty.	System	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:24:08

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:16
Data point term sent to Coder	System	03 Sep 2020 16:24:49
User entered 'Gastroesophageal reflux disease'	Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2014'	Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2014'	System	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2014'	System	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:24:36

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:47
Data point term sent to Coder	System	03 Sep 2020 16:25:51
User entered 'Benign prostatic hyperplasia'	Trent Davis (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1996'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1996'	System	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1996'	System	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:03

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Blindness unilateral, LLT: Blind left eye - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:49
Data point term sent to Coder	System	03 Sep 2020 16:25:52
User entered 'Blind Left eye'	Trent Davis (b) (4)	03 Sep 2020 16:25:27
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1986'	Trent Davis (b) (4)	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1986'	System	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1986'	System	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:27

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:26:49
Data point term sent to Coder	System	03 Sep 2020 16:25:53
User entered 'Sleep Apnea'	Trent Davis (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2000'	Trent Davis (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2000'	System	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2000'	System	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:25:49

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
Data point term sent to Coder	System	03 Sep 2020 16:26:53
User entered 'Seasonal Allergies'	Trent Davis (b) (4)	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:02:09
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:26:08
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	28 Oct 2020 16:02:17
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:02:17
	(b) (4)	
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	28 Oct 2020 16:02:09
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 16:26:08
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2000'	System	28 Oct 2020 16:02:09
User entered empty.	System	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2000'	System	28 Oct 2020 16:02:09
User entered empty.	System	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:08

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
Data point term sent to Coder	System	03 Sep 2020 16:26:54
User entered 'Anxiety'	Trent Davis (b) (4)	03 Sep 2020 16:26:28
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2020'	Trent Davis (b) (4)	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2020'	System	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2020'	System	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:28

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:27:51
Data point term sent to Coder	System	03 Sep 2020 16:26:54
User entered 'Obesity'	Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2020'	Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2020'	System	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2020'	System	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:26:50

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 05:44:46
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:07:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 15:07:23
Data point term sent to Coder	System	04 Nov 2020 15:06:27
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	04 Nov 2020 15:06:23
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	04 Nov 2020 15:06:13
User entered 'Sensory NEUROPATHY in both feet' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	04 Nov 2020 15:06:13
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:40:18
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:30:38

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Sep 2020 16:30:38
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 16:29:59
User entered 'Neuropathy'	Trent Davis (b) (4)	03 Sep 2020 16:29:28
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2010'	Trent Davis (b) (4)	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2010'	System	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2010'	System	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:29:28

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:32:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:32:44
Data point term sent to Coder	System	03 Sep 2020 16:32:06
User entered 'hypercholesterolemia'	Trent Davis (b) (4)	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1995' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:03:44
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:31:25
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	28 Oct 2020 16:03:55
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:03:55
	(b) (4)	
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	28 Oct 2020 16:03:44
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 16:31:25
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1995'	System	28 Oct 2020 16:03:44
User entered empty.	System	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1995'	System	28 Oct 2020 16:03:44
User entered empty.	System	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:31:25

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:37:47
Data point term sent to Coder	System	03 Sep 2020 16:37:20
User entered 'Vitamin D Deficiency'	Trent Davis (b) (4)	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:04:46
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:36:33
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0' reason for change: Data Entry Error	(b) (4) Thea Marie Cordero	28 Oct 2020 16:04:46
User entered '1'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:33
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2018'	System	28 Oct 2020 16:04:46
User entered empty.	System	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2018'	System	28 Oct 2020 16:04:46
User entered empty.	System	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:36:33

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Dry skin, LLT: Dry skin - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:37:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:37:46
Data point term sent to Coder	System	03 Sep 2020 16:37:21
User entered 'Dry SKin'	Trent Davis (b) (4)	03 Sep 2020 16:36:53
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2018'	Trent Davis (b) (4)	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:36:53

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Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2018'	System	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2018'	System	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 16:36:53

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: Human immunodeficiency virus syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 17:45:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 17:45:54
Data point term sent to Coder	System	03 Sep 2020 17:44:22
User entered 'human immunodeficiency virus'	Trent Davis (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 2014'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2014'	System	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2014'	System	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	03 Sep 2020 17:44:11

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Transurethral prostatectomy, LLT: Prostate transurethral resection - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 17:46:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 17:46:57
Data point term sent to Coder	System	03 Sep 2020 17:45:23
User entered 'Transurethral resection of the prostate'	Trent Davis (b) (4)	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un Mar 2010'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 09:27:36
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:26:09
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	27 Oct 2020 18:26:02
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:19:12
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:45:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 17:45:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:45:08
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un Mar 2010' reason for change: Data Entry Error	(b) (4)	27 Oct 2020 18:26:02
User entered empty.	Shetel Anassi (b) (4)	03 Sep 2020 17:45:04
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Mar 2010'	System	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2010'	System	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Mar 2010'	System	27 Oct 2020 18:26:02
User entered empty.	System	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2010'	System	27 Oct 2020 18:26:02
User entered empty.	System	03 Sep 2020 17:45:04

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 11:59:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 11:59:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 11:04:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 11:04:29
Data point term sent to Coder	System	28 Oct 2020 16:20:35
User entered 'Drug allergy: Bactrim (Rash)'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:19:51

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1998'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:19:51
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:19:51
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:19:51
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 16:19:51
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:19:51
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1998'	System	28 Oct 2020 16:19:51

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1998'	System	28 Oct 2020 16:19:51

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	28 Oct 2020 16:19:51

US3862110

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	28 Oct 2020 16:19:51

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus allergic, LLT: Drug-induced pruritus - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:47:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:47:50
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)	09 Nov 2020 11:18:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 11:18:29
Data point term sent to Coder	System	28 Oct 2020 16:21:36
User entered 'Drug Allergy: Hydrocodone (Itch)'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:21:06

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'un UNK 1998'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:21:06
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:21:06
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:21:06
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 16:21:06
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:21:06
	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 1998'	System	28 Oct 2020 16:21:06

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '1998'	System	28 Oct 2020 16:21:06

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	28 Oct 2020 16:21:06

US3862110

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	28 Oct 2020 16:21:06

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 22:58:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 22:58:36
Data point term sent to Coder	System	13 Nov 2020 22:58:09
User entered 'Diabetes Type 2'	Shetel Anassi (b) (4)	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'UN UNK 2014' reason for change:	(b) (4)	15 Dec 2020 19:11:24
New Information	Thea Marie Cordero	13 Nov 2020 22:57:40
User entered 'un UNK 2016'	(b) (4)	

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Shetel Anassi (b) (4)	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Shetel Anassi (b) (4)	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Shetel Anassi (b) (4)	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'Jan 2014'	System	15 Dec 2020 19:11:24
User entered 'Jan 2016'	System	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2014'	System	15 Dec 2020 19:11:24
User entered '2016'	System	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:04:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered empty.	System	13 Nov 2020 22:57:40

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:42'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '2 Sep 2020 10:42'	System	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '70.0' in	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 14:13:29
DataPoint set to visible.	(b) (4)	
	System	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '229.0' lb	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29
DataPoint set to visible.	(b) (4) System	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '32.92678'	System	03 Sep 2020 14:13:29
DataPoint set to visible.	System	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'kg/m2'	System	03 Sep 2020 14:13:29
DataPoint set to visible.	System	02 Sep 2020 17:26:09

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '97.8' F	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '072'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'bpm'	System	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '016'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'breaths/min'	System	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '122'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'mmHg'	System	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '092'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:13:29

US3862110

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'mmHg'	System	03 Sep 2020 14:13:29

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02

US3862110

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:18:16

US3862110

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:18:16

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:23
User entered empty.	System	03 Sep 2020 14:19:23
	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:19:23
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:23
User entered empty.	System	03 Sep 2020 14:19:23
	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 14:19:45
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 14:19:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 14:19:23
User entered empty.	System	03 Sep 2020 14:19:23
	Trent Davis (b) (4)	03 Sep 2020 14:19:23
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:19:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'I'	Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'I'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:19:23

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:19:23

US3862110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:20:25

US3862110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:20:25

US3862110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Clinic (Clinic)'	Trent Davis (b) (4)	03 Sep 2020 14:20:25

US3862110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'VISIT1'	System	03 Sep 2020 14:20:25

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:49:39

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '145531'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:49:39

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	02 Sep 2020 16:49:39

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

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)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:09:05
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Completed' (Site from DM).	Coni Cheesman (b) (4) (b) (4)	04 Sep 2020 00:43:29
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:28:12
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:21:00

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

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)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 14:21:00

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 14:21:00

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 14:21:00

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 14:21:00

US3862110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:33

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 18:32:05
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 04:54:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:54:19

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 06:59:34
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'ND recorded' (Site from DM).	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:53
User entered missing code ND - Not Done; reason for change New Information	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:45
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:33:00
User entered '70.0' in	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered missing code ND - Not Done; reason for change New Information	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:28:45
User entered '229.0' lb	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 06:59:34
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'ND recorded' (Site from DM).	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:53
User entered missing code ND - Not Done; reason for change New Information	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:45
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:33:00
User entered '70.0' in	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered missing code ND - Not Done; reason for change New Information	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:28:45
User entered '229.0' lb	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:42'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '2 Sep 2020 10:42'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '97.8' F	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '072'	Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'bpm'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'breaths/min'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '122'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '092'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 06:59:34
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'ND recorded' (Site from DM).	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:53
User entered missing code ND - Not Done; reason for change New Information	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 22:28:45
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:33:00
User entered '70.0' in	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered missing code ND - Not Done; reason for change New Information	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:28:45
User entered '229.0' lb	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '12:27'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '2 Sep 2020 12:27'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '97.8' F	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '70'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'bpm'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '018'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'breaths/min'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '129'	Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '089'	Trent Davis (b) (4)	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	03 Sep 2020 16:01:25

US3862110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 15:49:30

US3862110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	Trent Davis (b) (4)	03 Sep 2020 15:49:30

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

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)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:36
	(b) (4)	

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	Trent Davis (b) (4)	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '11:57'	(b) (4) Trent Davis (b) (4)	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '2 Sep 2020 11:57'	System	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Right Arm (RIGHT ARM)'	Trent Davis (b) (4)	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'ONCE'	System	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 17:26:36

US3862110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 15:50:53

US3862110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:50:53
	(b) (4)	

US3862110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '11:32'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 15:50:53

US3862110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '2 Sep 2020 11:32'	System	03 Sep 2020 15:50:53

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '2 Sep 2020'	Trent Davis (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '11:15'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '2 Sep 2020 11:15'	System	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered empty.	System	03 Sep 2020 15:51:29

US3862110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 15:51:35

US3862110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	03 Sep 2020 15:51:35

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:28:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f57a7a2c-c430-461b-800b-6229d93119cc'	System	02 Sep 2020 17:29:27
User entered 'Yes (Y)'	System	02 Sep 2020 17:29:27

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:28:01', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f57a7a2c-c430-461b-800b-6229d93119cc'	System	02 Sep 2020 17:29:27
User entered '97.8'	System	02 Sep 2020 17:29:27

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:28:49', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f57a7a2c-c430-461b-800b-6229d93119cc'	System	02 Sep 2020 17:29:27
User entered 'No (N)'	System	02 Sep 2020 17:29:27

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:29:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f57a7a2c-c430-461b-800b-6229d93119cc'	System	02 Sep 2020 17:29:27
User entered '02 Sep 2020 12:29'	System	02 Sep 2020 17:29:27

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 12:17'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 14:47'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:39', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f5ad0718-3f3a-4974-a2ac-c25cd79401d8'	System	02 Sep 2020 23:44:00
User entered 'Yes (Y)'	System	02 Sep 2020 23:44:00

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:48', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f5ad0718-3f3a-4974-a2ac-c25cd79401d8'	System	02 Sep 2020 23:44:00
User entered '97.6'	System	02 Sep 2020 23:44:00

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f5ad0718-3f3a-4974-a2ac-c25cd79401d8'	System	02 Sep 2020 23:44:00
User entered 'No (N)'	System	02 Sep 2020 23:44:00

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f5ad0718-3f3a-4974-a2ac-c25cd79401d8'	System	02 Sep 2020 23:44:00
User entered '02 Sep 2020 18:43'	System	02 Sep 2020 23:44:00

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 15:42'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 2'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:25:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3813c570-09e6-4096-9cac-d76718ad546f'	System	03 Sep 2020 18:26:13
User entered 'Yes (Y)'	System	03 Sep 2020 18:26:13

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:25:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3813c570-09e6-4096-9cac-d76718ad546f' User entered '97.7'	System	03 Sep 2020 18:26:13
	System	03 Sep 2020 18:26:13

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:25:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3813c570-09e6-4096-9cac-d76718ad546f'	System	03 Sep 2020 18:26:13
User entered 'No (N)'	System	03 Sep 2020 18:26:13

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3813c570-09e6-4096-9cac-d76718ad546f' User entered '03 Sep 2020 13:26'	System	03 Sep 2020 18:26:13
	System	03 Sep 2020 18:26:13

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 3'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:28:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'eb83283e-ea11-49a7-93fc-359dc4e988e6'	System	05 Sep 2020 01:28:41
User entered 'Yes (Y)'	System	05 Sep 2020 01:28:41

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:28:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'eb83283e-ea11-49a7-93fc-359dc4e988e6'	System	05 Sep 2020 01:28:41
User entered '97.6'	System	05 Sep 2020 01:28:41

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:28:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'eb83283e-ea11-49a7-93fc-359dc4e988e6'	System	05 Sep 2020 01:28:41
User entered 'No (N)'	System	05 Sep 2020 01:28:41

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:28:39', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'eb83283e-ea11-49a7-93fc-359dc4e988e6'	System	05 Sep 2020 01:28:41
User entered '04 Sep 2020 20:28'	System	05 Sep 2020 01:28:41

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 4'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:37:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b8c5ecc8-b1ee-4041-b019-0c6156d6d1fd'	System	06 Sep 2020 01:38:10
User entered 'Yes (Y)'	System	06 Sep 2020 01:38:10

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:37:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b8c5ecc8-b1ee-4041-b019-0c6156d6d1fd'	System	06 Sep 2020 01:38:10
User entered '97.0'	System	06 Sep 2020 01:38:10

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b8c5ecc8-b1ee-4041-b019-0c6156d6d1fd'	System	06 Sep 2020 01:38:10
User entered 'No (N)'	System	06 Sep 2020 01:38:10

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:06', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b8c5ecc8-b1ee-4041-b019-0c6156d6d1fd'	System	06 Sep 2020 01:38:10
User entered '05 Sep 2020 20:38'	System	06 Sep 2020 01:38:10

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 5'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:01:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5cd99785-3fdb-45ff-97d8-ecf5d4d8b6bb'	System	06 Sep 2020 17:02:48
User entered 'Yes (Y)'	System	06 Sep 2020 17:02:48

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:11', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5cd99785-3fdb-45ff-97d8-ecf5d4d8b6bb'	System	06 Sep 2020 17:02:48
User entered '97.8'	System	06 Sep 2020 17:02:48

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:15', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5cd99785-3fdb-45ff-97d8-ecf5d4d8b6bb'	System	06 Sep 2020 17:02:48
User entered 'No (N)'	System	06 Sep 2020 17:02:48

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:18', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5cd99785-3fdb-45ff-97d8-ecf5d4d8b6bb'	System	06 Sep 2020 17:02:48
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:48

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 6'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:48:41', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e033eb41-1292-403e-a338-9b477536e05d'	System	07 Sep 2020 20:49:06
User entered 'Yes (Y)'	System	07 Sep 2020 20:49:06

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:48:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e033eb41-1292-403e-a338-9b477536e05d' User entered '97.8'	System	07 Sep 2020 20:49:06
	System	07 Sep 2020 20:49:06

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:48:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e033eb41-1292-403e-a338-9b477536e05d'	System	07 Sep 2020 20:49:06
User entered 'No (N)'	System	07 Sep 2020 20:49:06

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:01', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e033eb41-1292-403e-a338-9b477536e05d'	System	07 Sep 2020 20:49:06
User entered '07 Sep 2020 15:49'	System	07 Sep 2020 20:49:06

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 7'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:06', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5dda70fa-3cf3-492c-8e8d-92809b1ff9ee'	System	08 Sep 2020 17:29:44
User entered 'Yes (Y)'	System	08 Sep 2020 17:29:44

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5dda70fa-3cf3-492c-8e8d-92809b1ff9ee'	System	08 Sep 2020 17:29:44
User entered '98.7'	System	08 Sep 2020 17:29:44

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5dda70fa-3cf3-492c-8e8d-92809b1ff9ee'	System	08 Sep 2020 17:29:44
User entered 'No (N)'	System	08 Sep 2020 17:29:44

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5dda70fa-3cf3-492c-8e8d-92809b1ff9ee'	System	08 Sep 2020 17:29:44
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 17:29:44

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:29:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'af91bd90-011c-4eec-9fdd-a8f840b3fe89'	System	02 Sep 2020 17:30:27
User entered 'None (1)'	System	02 Sep 2020 17:30:27

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:06', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'af91bd90-011c-4eec-9fdd-a8f840b3fe89'	System	02 Sep 2020 17:30:27
User entered 'No (N)'	System	02 Sep 2020 17:30:27

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'af91bd90-011c-4eec-9fdd-a8f840b3fe89'	System	02 Sep 2020 17:30:27
User entered 'No (N)'	System	02 Sep 2020 17:30:27

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:20', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'af91bd90-011c-4eec-9fdd-a8f840b3fe89'	System	02 Sep 2020 17:30:27
User entered 'None (1)'	System	02 Sep 2020 17:30:27

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:25', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'af91bd90-011c-4eec-9fdd-a8f840b3fe89'	System	02 Sep 2020 17:30:27
User entered '02 Sep 2020 12:30'	System	02 Sep 2020 17:30:27

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 12:17'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 14:47'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:02', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9f991beb-4760-4656-a7fd-dfe2ea55e1e9'	System	02 Sep 2020 23:43:29
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 23:43:29

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9f991beb-4760-4656-a7fd-dfe2ea55e1e9'	System	02 Sep 2020 23:43:29
User entered 'No (N)'	System	02 Sep 2020 23:43:29

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9f991beb-4760-4656-a7fd-dfe2ea55e1e9'	System	02 Sep 2020 23:43:29
User entered 'No (N)'	System	02 Sep 2020 23:43:29

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9f991beb-4760-4656-a7fd-dfe2ea55e1e9'	System	02 Sep 2020 23:43:29
User entered 'None (1)'	System	02 Sep 2020 23:43:29

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:43:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9f991beb-4760-4656-a7fd-dfe2ea55e1e9'	System	02 Sep 2020 23:43:29
User entered '02 Sep 2020 18:43'	System	02 Sep 2020 23:43:29

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 15:42'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 2'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:15', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '96a20747-75f1-4e31-830d-c1ec1d791623'	System	03 Sep 2020 18:26:39
User entered 'None (1)'	System	03 Sep 2020 18:26:39

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '96a20747-75f1-4e31-830d-c1ec1d791623'	System	03 Sep 2020 18:26:39
User entered 'No (N)'	System	03 Sep 2020 18:26:39

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '96a20747-75f1-4e31-830d-c1ec1d791623'	System	03 Sep 2020 18:26:39
User entered 'No (N)'	System	03 Sep 2020 18:26:39

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '96a20747-75f1-4e31-830d-c1ec1d791623'	System	03 Sep 2020 18:26:39
User entered 'None (1)'	System	03 Sep 2020 18:26:39

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:36', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '96a20747-75f1-4e31-830d-c1ec1d791623'	System	03 Sep 2020 18:26:39
User entered '03 Sep 2020 13:26'	System	03 Sep 2020 18:26:39

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 3'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:29:37', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'cfb1864c-b046-47db-8c48-58fd407036ed'	System	05 Sep 2020 01:29:54
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:29:54

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:29:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'cfb1864c-b046-47db-8c48-58fd407036ed'	System	05 Sep 2020 01:29:54
User entered 'No (N)'	System	05 Sep 2020 01:29:54

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:29:43', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'cfb1864c-b046-47db-8c48-58fd407036ed'	System	05 Sep 2020 01:29:54
User entered 'No (N)'	System	05 Sep 2020 01:29:54

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:29:48', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'cfb1864c-b046-47db-8c48-58fd407036ed'	System	05 Sep 2020 01:29:54
User entered 'None (1)'	System	05 Sep 2020 01:29:54

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:29:51', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'cfb1864c-b046-47db-8c48-58fd407036ed'	System	05 Sep 2020 01:29:54
User entered '04 Sep 2020 20:29'	System	05 Sep 2020 01:29:54

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 4'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2e8623c0-0b65-4819-a1ef-78238c342ad3'	System	06 Sep 2020 01:38:34
User entered 'None (1)'	System	06 Sep 2020 01:38:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2e8623c0-0b65-4819-a1ef-78238c342ad3'	System	06 Sep 2020 01:38:34
User entered 'No (N)'	System	06 Sep 2020 01:38:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2e8623c0-0b65-4819-a1ef-78238c342ad3'	System	06 Sep 2020 01:38:34
User entered 'No (N)'	System	06 Sep 2020 01:38:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:27', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2e8623c0-0b65-4819-a1ef-78238c342ad3'	System	06 Sep 2020 01:38:34
User entered 'None (1)'	System	06 Sep 2020 01:38:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:32', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2e8623c0-0b65-4819-a1ef-78238c342ad3'	System	06 Sep 2020 01:38:34
User entered '05 Sep 2020 20:38'	System	06 Sep 2020 01:38:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 5'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'df621968-89d8-4c40-9eef-41ab1016006b'	System	06 Sep 2020 17:03:21
User entered 'None (1)'	System	06 Sep 2020 17:03:21

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:51', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'df621968-89d8-4c40-9eef-41ab1016006b'	System	06 Sep 2020 17:03:21
User entered 'No (N)'	System	06 Sep 2020 17:03:21

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'df621968-89d8-4c40-9eef-41ab1016006b'	System	06 Sep 2020 17:03:21
User entered 'No (N)'	System	06 Sep 2020 17:03:21

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'df621968-89d8-4c40-9eef-41ab1016006b'	System	06 Sep 2020 17:03:21
User entered 'None (1)'	System	06 Sep 2020 17:03:21

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:03:01', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'df621968-89d8-4c40-9eef-41ab1016006b'	System	06 Sep 2020 17:03:21
User entered '06 Sep 2020 12:03'	System	06 Sep 2020 17:03:21

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 6'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:17', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5a4a2c8a-e5a0-4946-b636-4d083fa108a5'	System	07 Sep 2020 20:49:34
User entered 'None (1)'	System	07 Sep 2020 20:49:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:20', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5a4a2c8a-e5a0-4946-b636-4d083fa108a5'	System	07 Sep 2020 20:49:34
User entered 'No (N)'	System	07 Sep 2020 20:49:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:23', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5a4a2c8a-e5a0-4946-b636-4d083fa108a5'	System	07 Sep 2020 20:49:34
User entered 'No (N)'	System	07 Sep 2020 20:49:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:26', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5a4a2c8a-e5a0-4946-b636-4d083fa108a5'	System	07 Sep 2020 20:49:34
User entered 'None (1)'	System	07 Sep 2020 20:49:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:49:32', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5a4a2c8a-e5a0-4946-b636-4d083fa108a5'	System	07 Sep 2020 20:49:34
User entered '07 Sep 2020 15:49'	System	07 Sep 2020 20:49:34

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 7'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2725c30f-c70d-454c-93db-20f2f0594d2f'	System	08 Sep 2020 17:30:15
User entered 'None (1)'	System	08 Sep 2020 17:30:15

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:29:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2725c30f-c70d-454c-93db-20f2f0594d2f'	System	08 Sep 2020 17:30:15
User entered 'No (N)'	System	08 Sep 2020 17:30:15

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2725c30f-c70d-454c-93db-20f2f0594d2f'	System	08 Sep 2020 17:30:15
User entered 'No (N)'	System	08 Sep 2020 17:30:15

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:05', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2725c30f-c70d-454c-93db-20f2f0594d2f'	System	08 Sep 2020 17:30:15
User entered 'None (1)'	System	08 Sep 2020 17:30:15

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:11', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2725c30f-c70d-454c-93db-20f2f0594d2f' User entered '08 Sep 2020 12:30'	System	08 Sep 2020 17:30:15
	System	08 Sep 2020 17:30:15

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:31', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:36', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:48', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:30:50', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'None (0)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:31:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered 'No (N)'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T12:31:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ca28c5a-0067-409e-abd4-34b253e448bf'	System	02 Sep 2020 17:31:09
User entered '02 Sep 2020 12:31'	System	02 Sep 2020 17:31:09

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 12:17'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 14:47'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:05', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:13', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:17', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:22', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:25', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'None (0)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:31', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered 'No (N)'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-02T18:42:35', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4e8d6e75-50e6-4bda-8d3b-f17765b30ca0'	System	02 Sep 2020 23:42:36
User entered '02 Sep 2020 18:42'	System	02 Sep 2020 23:42:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Sep 2020 15:42'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 2'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:49', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:51', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'None (0)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered 'No (N)'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-03T13:26:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '38056bba-be6f-4984-9f5e-5d7491a9e9ad'	System	03 Sep 2020 18:26:59
User entered '03 Sep 2020 13:26'	System	03 Sep 2020 18:26:59

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 3'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:06', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:20', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:22', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:25', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'None (0)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'None (0)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered 'No (N)'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-04T20:30:38', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f7123686-a988-4073-a69a-b70d79352094'	System	05 Sep 2020 01:30:42
User entered '04 Sep 2020 20:30'	System	05 Sep 2020 01:30:42

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 4'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:44', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:50', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:52', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:38:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:39:02', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:39:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'None (0)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:39:11', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered 'No (N)'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-05T20:39:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '3df0b166-dfdc-478b-9464-bb6c5a9f6851'	System	06 Sep 2020 01:39:18
User entered '05 Sep 2020 20:39'	System	06 Sep 2020 01:39:18

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 5'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:23', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:26', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:30', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:35', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:37', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'None (0)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered 'No (N)'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-06T12:02:43', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b92f12ec-b585-489a-bc65-18ad2f048a77'	System	06 Sep 2020 17:03:11
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:03:11

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 6'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:09', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:12', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'None (0)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered 'No (N)'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-07T15:50:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6f7c68af-8a4e-4e36-9b01-fb463067dada'	System	07 Sep 2020 20:50:23
User entered '07 Sep 2020 15:50'	System	07 Sep 2020 20:50:23

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 7'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:32', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:38', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:44', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'None (0)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:49', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered 'No (N)'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-08T12:30:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ddc16ced-ad88-4c05-93fe-ca804b69ddc9'	System	08 Sep 2020 17:31:02
User entered '08 Sep 2020 12:30'	System	08 Sep 2020 17:31:02

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:26:36

US3862110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 20:07:52

US3862110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 20:07:52
	(b) (4)	

US3862110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 20:07:52

US3862110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 20:07:52
	(b) (4)	

US3862110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:10:49

US3862110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	18 Sep 2020 23:10:49

US3862110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:10:58

US3862110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '18 Sep 2020'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:10:58

US3862110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:10:58

US3862110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:10:58
	(b) (4)	

US3862110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 23:11:14

US3862110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	18 Sep 2020 23:11:14

US3862110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	23 Sep 2020 17:53:23

US3862110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '23 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	23 Sep 2020 17:53:23
	(b) (4)	

US3862110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Coni Cheesman (b) (4)	23 Sep 2020 17:53:23

US3862110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Coni Cheesman (b) (4)	23 Sep 2020 17:53:23
	(b) (4)	

US3862110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:35:13

US3862110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	30 Sep 2020 16:35:13

US3862110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:21:05

US3862110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:21:05

US3862110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Clinic (Clinic)'	Trent Davis (b) (4)	30 Sep 2020 21:21:05

US3862110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'VISIT2'	System	30 Sep 2020 21:21:05

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:02'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '30 Sep 2020 10:02'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '098.3' F	Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '067'	Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'bpm'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '012'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'breaths/min'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '138'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '092'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '11:50'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '30 Sep 2020 11:50'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '097.7' F	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Other (Other)'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'temporal'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '062'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'bpm'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '020'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'breaths/min'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '138'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '094'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	30 Sep 2020 21:22:35

US3862110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	Trent Davis (b) (4)	30 Sep 2020 21:20:57

US3862110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:20:57

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

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)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	Trent Davis (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	Trent Davis (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '11:20'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '30 Sep 2020 11:20'	System	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Right Arm (RIGHT ARM)'	Trent Davis (b) (4)	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'ONCE'	System	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:36:00

US3862110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:59

US3862110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 21:22:59
	(b) (4)	

US3862110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:50'	(b) (4) Trent Davis (b) (4) (b) (4)	30 Sep 2020 21:22:59

US3862110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '30 Sep 2020 10:50'	System	30 Sep 2020 21:22:59

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:33

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '30 Sep 2020'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered empty.	System	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:36'	Trent Davis (b) (4)	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '30 Sep 2020 10:36'	System	30 Sep 2020 16:49:07

US3862110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	07 Oct 2020 18:59:00
	(b) (4)	

US3862110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	07 Oct 2020 18:59:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:40:23', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '95581f11-f122-40ee-8948-6096e67d601f'	System	30 Sep 2020 16:40:45
User entered 'Yes (Y)'	System	30 Sep 2020 16:40:45

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:40:29', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '95581f11-f122-40ee-8948-6096e67d601f' User entered '98.0'	System	30 Sep 2020 16:40:45
	System	30 Sep 2020 16:40:45

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:40:34', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '95581f11-f122-40ee-8948-6096e67d601f'	System	30 Sep 2020 16:40:45
User entered 'No (N)'	System	30 Sep 2020 16:40:45

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:40:41', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '95581f11-f122-40ee-8948-6096e67d601f'	System	30 Sep 2020 16:40:45
User entered '30 Sep 2020 11:40'	System	30 Sep 2020 16:40:45

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 11:40'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 14:10'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:53:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '589d9f07-847c-4635-9aab-5584bd8a1af8'	System	01 Oct 2020 04:53:43
User entered 'Yes (Y)'	System	01 Oct 2020 04:53:43

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:53:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '589d9f07-847c-4635-9aab-5584bd8a1af8'	System	01 Oct 2020 04:53:43
User entered '97.6'	System	01 Oct 2020 04:53:43

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:53:37', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '589d9f07-847c-4635-9aab-5584bd8a1af8'	System	01 Oct 2020 04:53:43
User entered 'No (N)'	System	01 Oct 2020 04:53:43

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:53:41', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '589d9f07-847c-4635-9aab-5584bd8a1af8'	System	01 Oct 2020 04:53:43
User entered '30 Sep 2020 23:53'	System	01 Oct 2020 04:53:43

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 15:05'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 2'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:09', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2d56def9-68da-435f-8cad-48d42da6f39f'	System	01 Oct 2020 21:48:48
User entered 'Yes (Y)'	System	01 Oct 2020 21:48:48

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:36', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2d56def9-68da-435f-8cad-48d42da6f39f'	System	01 Oct 2020 21:48:48
User entered '97.5'	System	01 Oct 2020 21:48:48

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2d56def9-68da-435f-8cad-48d42da6f39f'	System	01 Oct 2020 21:48:48
User entered 'No (N)'	System	01 Oct 2020 21:48:48

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:43', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2d56def9-68da-435f-8cad-48d42da6f39f'	System	01 Oct 2020 21:48:48
User entered '01 Oct 2020 16:48'	System	01 Oct 2020 21:48:48

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 3'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:45:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '970cd2bc-af67-4dc2-8704-c6e13326eac'	System	02 Oct 2020 19:46:16
User entered 'Yes (Y)'	System	02 Oct 2020 19:46:16

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '970cd2bc-af67-4dc2-8704-c6e13326eac'	System	02 Oct 2020 19:46:16
User entered '98.6'	System	02 Oct 2020 19:46:16

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:09', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '970cd2bc-af67-4dc2-8704-c6e13326eac'	System	02 Oct 2020 19:46:16
User entered 'No (N)'	System	02 Oct 2020 19:46:16

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '970cd2bc-af67-4dc2-8704-c6e13326eac'	System	02 Oct 2020 19:46:16
User entered '02 Oct 2020 14:46'	System	02 Oct 2020 19:46:16

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 4'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 5'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0956dea7-2ccc-453d-af43-5ec3c1567c75'	System	05 Oct 2020 02:11:34
User entered 'Yes (Y)'	System	05 Oct 2020 02:11:34

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0956dea7-2ccc-453d-af43-5ec3c1567c75'	System	05 Oct 2020 02:11:34
User entered '98.6'	System	05 Oct 2020 02:11:34

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:18', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0956dea7-2ccc-453d-af43-5ec3c1567c75'	System	05 Oct 2020 02:11:34
User entered 'No (N)'	System	05 Oct 2020 02:11:34

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:31', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0956dea7-2ccc-453d-af43-5ec3c1567c75'	System	05 Oct 2020 02:11:34
User entered '04 Oct 2020 21:11'	System	05 Oct 2020 02:11:34

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 6'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd58588cc-c87a-406f-a40b-4b7db4495258'	System	05 Oct 2020 23:59:44
User entered 'Yes (Y)'	System	05 Oct 2020 23:59:44

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:27', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd58588cc-c87a-406f-a40b-4b7db4495258'	System	05 Oct 2020 23:59:44
User entered '97.6'	System	05 Oct 2020 23:59:44

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:35', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd58588cc-c87a-406f-a40b-4b7db4495258'	System	05 Oct 2020 23:59:44
User entered 'No (N)'	System	05 Oct 2020 23:59:44

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:39', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd58588cc-c87a-406f-a40b-4b7db4495258'	System	05 Oct 2020 23:59:44
User entered '05 Oct 2020 18:59'	System	05 Oct 2020 23:59:44

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 7'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:55:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '46da65aa-798a-4ed1-b022-5fc85c9352c6'	System	06 Oct 2020 21:56:42
User entered 'Yes (Y)'	System	06 Oct 2020 21:56:42

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '46da65aa-798a-4ed1-b022-5fc85c9352c6'	System	06 Oct 2020 21:56:42
User entered '97.6'	System	06 Oct 2020 21:56:42

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:22', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '46da65aa-798a-4ed1-b022-5fc85c9352c6'	System	06 Oct 2020 21:56:42
User entered 'No (N)'	System	06 Oct 2020 21:56:42

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '46da65aa-798a-4ed1-b022-5fc85c9352c6'	System	06 Oct 2020 21:56:42
User entered '06 Oct 2020 16:56'	System	06 Oct 2020 21:56:42

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:40:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5015815f-a734-4f88-8ece-8a3dfa14a1a1'	System	30 Sep 2020 16:41:26
User entered 'None (1)'	System	30 Sep 2020 16:41:26

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:05', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5015815f-a734-4f88-8ece-8a3dfa14a1a1'	System	30 Sep 2020 16:41:26
User entered 'No (N)'	System	30 Sep 2020 16:41:26

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5015815f-a734-4f88-8ece-8a3dfa14a1a1'	System	30 Sep 2020 16:41:26
User entered 'No (N)'	System	30 Sep 2020 16:41:26

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5015815f-a734-4f88-8ece-8a3dfa14a1a1'	System	30 Sep 2020 16:41:26
User entered 'None (1)'	System	30 Sep 2020 16:41:26

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5015815f-a734-4f88-8ece-8a3dfa14a1a1'	System	30 Sep 2020 16:41:26
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 16:41:26

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 11:40'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 14:10'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:53:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c3c24ca0-bae9-4574-b2df-4346df727944'	System	01 Oct 2020 04:54:15
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 04:54:15

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c3c24ca0-bae9-4574-b2df-4346df727944'	System	01 Oct 2020 04:54:15
User entered 'No (N)'	System	01 Oct 2020 04:54:15

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c3c24ca0-bae9-4574-b2df-4346df727944'	System	01 Oct 2020 04:54:15
User entered 'No (N)'	System	01 Oct 2020 04:54:15

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c3c24ca0-bae9-4574-b2df-4346df727944'	System	01 Oct 2020 04:54:15
User entered 'None (1)'	System	01 Oct 2020 04:54:15

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c3c24ca0-bae9-4574-b2df-4346df727944'	System	01 Oct 2020 04:54:15
User entered '30 Sep 2020 23:54'	System	01 Oct 2020 04:54:15

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 15:05'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 2'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:11', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6a4c188d-f197-4a02-9cbc-3f1f3734e255'	System	01 Oct 2020 21:49:16
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 21:49:16

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6a4c188d-f197-4a02-9cbc-3f1f3734e255'	System	01 Oct 2020 21:49:16
User entered 'No (N)'	System	01 Oct 2020 21:49:16

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:48:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6a4c188d-f197-4a02-9cbc-3f1f3734e255'	System	01 Oct 2020 21:49:16
User entered 'No (N)'	System	01 Oct 2020 21:49:16

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6a4c188d-f197-4a02-9cbc-3f1f3734e255'	System	01 Oct 2020 21:49:16
User entered 'None (1)'	System	01 Oct 2020 21:49:16

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6a4c188d-f197-4a02-9cbc-3f1f3734e255'	System	01 Oct 2020 21:49:16
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 21:49:16

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 3'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:18', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c62b4c8c-af65-4ce3-9491-1446fa1ecd1d'	System	02 Oct 2020 19:46:37
User entered 'None (1)'	System	02 Oct 2020 19:46:37

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:22', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c62b4c8c-af65-4ce3-9491-1446fa1ecd1d'	System	02 Oct 2020 19:46:37
User entered 'No (N)'	System	02 Oct 2020 19:46:37

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:25', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c62b4c8c-af65-4ce3-9491-1446fa1ecd1d'	System	02 Oct 2020 19:46:37
User entered 'No (N)'	System	02 Oct 2020 19:46:37

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c62b4c8c-af65-4ce3-9491-1446fa1ecd1d'	System	02 Oct 2020 19:46:37
User entered 'None (1)'	System	02 Oct 2020 19:46:37

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'c62b4c8c-af65-4ce3-9491-1446fa1ecd1d' User entered '02 Oct 2020 14:46'	System	02 Oct 2020 19:46:37
	System	02 Oct 2020 19:46:37

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 4'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 5'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '203821e8-f034-4df9-bfd2-0dcafcabcd26b'	System	05 Oct 2020 02:11:56
User entered 'None (1)'	System	05 Oct 2020 02:11:56

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '203821e8-f034-4df9-bfd2-0dcafcabcd26b'	System	05 Oct 2020 02:11:56
User entered 'No (N)'	System	05 Oct 2020 02:11:56

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:46', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '203821e8-f034-4df9-bfd2-0dcafcabcd26b'	System	05 Oct 2020 02:11:56
User entered 'No (N)'	System	05 Oct 2020 02:11:56

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:50', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '203821e8-f034-4df9-bfd2-0dcafcabcd26b'	System	05 Oct 2020 02:11:56
User entered 'None (1)'	System	05 Oct 2020 02:11:56

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:11:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '203821e8-f034-4df9-bfd2-0dcafcabcd26b'	System	05 Oct 2020 02:11:56
User entered '04 Oct 2020 21:11'	System	05 Oct 2020 02:11:56

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 6'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5f8a8322-d330-4ef0-90a8-4af3984e87f7'	System	06 Oct 2020 00:00:19
User entered 'None (1)'	System	06 Oct 2020 00:00:19

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:48', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5f8a8322-d330-4ef0-90a8-4af3984e87f7'	System	06 Oct 2020 00:00:19
User entered 'No (N)'	System	06 Oct 2020 00:00:19

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T18:59:51', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5f8a8322-d330-4ef0-90a8-4af3984e87f7'	System	06 Oct 2020 00:00:19
User entered 'No (N)'	System	06 Oct 2020 00:00:19

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:00:13', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5f8a8322-d330-4ef0-90a8-4af3984e87f7'	System	06 Oct 2020 00:00:19
User entered 'None (1)'	System	06 Oct 2020 00:00:19

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:00:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5f8a8322-d330-4ef0-90a8-4af3984e87f7'	System	06 Oct 2020 00:00:19
User entered '05 Oct 2020 19:00'	System	06 Oct 2020 00:00:19

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 7'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd705064f-6432-4ada-b8de-ec54c0c4112c'	System	06 Oct 2020 21:56:55
User entered 'None (1)'	System	06 Oct 2020 21:56:55

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:37', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd705064f-6432-4ada-b8de-ec54c0c4112c'	System	06 Oct 2020 21:56:55
User entered 'No (N)'	System	06 Oct 2020 21:56:55

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:41', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd705064f-6432-4ada-b8de-ec54c0c4112c'	System	06 Oct 2020 21:56:55
User entered 'No (N)'	System	06 Oct 2020 21:56:55

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd705064f-6432-4ada-b8de-ec54c0c4112c'	System	06 Oct 2020 21:56:55
User entered 'None (1)'	System	06 Oct 2020 21:56:55

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd705064f-6432-4ada-b8de-ec54c0c4112c'	System	06 Oct 2020 21:56:55
User entered '06 Oct 2020 16:56'	System	06 Oct 2020 21:56:55

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'None (0)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:37', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'None (0)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'None (0)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e' User entered 'None (0)'	System	30 Sep 2020 16:41:59
	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'None (0)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'None (0)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered 'No (N)'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T11:41:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'aa49b545-2c02-4732-b1e9-5443b75e3d1e'	System	30 Sep 2020 16:41:59
User entered '30 Sep 2020 11:41'	System	30 Sep 2020 16:41:59

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 11:40'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 14:10'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:21', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:26', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:30', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'None (0)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered 'No (N)'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-09-30T23:54:36', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'deaeb888-bb58-4628-97e8-516acc1ef077'	System	01 Oct 2020 04:54:38
User entered '30 Sep 2020 23:54'	System	01 Oct 2020 04:54:38

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '30 Sep 2020 15:05'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 2'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:28', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'No interference with activity (1)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:35', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'None (0)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:49:59', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'None (0)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:50:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'None (0)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:50:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'None (0)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:50:13', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'None (0)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:50:15', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered 'No (N)'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-01T16:50:18', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '349c520b-773c-4435-af12-c99c115340d8'	System	01 Oct 2020 21:50:21
User entered '01 Oct 2020 16:50'	System	01 Oct 2020 21:50:21

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 3'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:38', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'None (0)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:41', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'None (0)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:44', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469' User entered 'None (0)'	System	02 Oct 2020 19:47:02
	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:46', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'None (0)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:49', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'None (0)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'None (0)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered 'No (N)'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-02T14:46:59', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1eb206d3-a24c-4b38-b759-ae2c98e52469'	System	02 Oct 2020 19:47:02
User entered '02 Oct 2020 14:46'	System	02 Oct 2020 19:47:02

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 4'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 5'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'None (0)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'None (0)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:13', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'No interference with activity (1)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'No interference with activity (1)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:33', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:38', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'None (0)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:12:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered 'No (N)'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-04T21:13:02', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f4fe973b-6f0d-4a2f-b35d-c239ed2b0884'	System	05 Oct 2020 02:13:06
User entered '04 Oct 2020 21:13'	System	05 Oct 2020 02:13:06

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 6'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:39', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:42', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:44', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:46', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:49', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:52', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'None (0)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:54', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered 'No (N)'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-05T19:01:57', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'f12409eb-38b6-4baa-b34d-f75f3a5f3837'	System	06 Oct 2020 00:02:01
User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:02:01

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
Data entry locked.	System	30 Sep 2020 16:36:00
User entered 'Day 7'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:56:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:57:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:57:02', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:57:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'None (0)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

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 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:57:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered 'No (N)'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-10-06T16:57:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9316c82d-2851-4782-b618-af9f95ef0da6'	System	06 Oct 2020 21:57:14
User entered '06 Oct 2020 16:57'	System	06 Oct 2020 21:57:14

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:36:00

US3862110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:04:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:46
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:36:00

US3862110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	07 Oct 2020 19:04:54
	(b) (4)	

US3862110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '7 Oct 2020'	(b) (4) Thea Marie Cordero	07 Oct 2020 19:04:54
	(b) (4)	

US3862110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero (b) (4)	07 Oct 2020 19:04:54

US3862110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Thea Marie Cordero	07 Oct 2020 19:04:54
	(b) (4)	

US3862110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	07 Oct 2020 19:04:58
	(b) (4)	

US3862110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	07 Oct 2020 19:04:58

US3862110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:09:28

US3862110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '14 Oct 2020'	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:09:28

US3862110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:09:28

US3862110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:09:28

US3862110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	14 Oct 2020 22:09:32

US3862110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	14 Oct 2020 22:09:32

US3862110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:19:28
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'data entered' (Site from DM).	Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:02:22
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 28OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:25:58
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	21 Oct 2020 23:21:08

US3862110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '21 Oct 2020'	(b) (4) Chanei Henry (b) (4)	21 Oct 2020 23:21:08

US3862110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	21 Oct 2020 23:21:08

US3862110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	21 Oct 2020 23:21:08

US3862110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	21 Oct 2020 23:21:12

US3862110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	21 Oct 2020 23:21:12

US3862110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:10

US3862110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '28 Oct 2020'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:10

US3862110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Clinic (Clinic)'	Trent Davis (b) (4)	13 Nov 2020 18:00:10

US3862110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'VISIT3'	System	13 Nov 2020 18:00:10

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '28 Oct 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:10'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '28 Oct 2020 10:10'	System	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '098.7' F	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Other (Other)'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'temporal'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '081'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'bpm'	System	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '016'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'breaths/min'	System	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '130'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '082'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'mmHg'	System	13 Nov 2020 18:00:47

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36

US3862110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36

US3862110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:01:00

US3862110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '28 Oct 2020'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:01:00
	(b) (4)	

US3862110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:01:26

US3862110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '28 Oct 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	13 Nov 2020 18:01:26

US3862110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered '10:29'	(b) (4) Trent Davis (b) (4)	13 Nov 2020 18:01:26

US3862110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered '28 Oct 2020 10:29'	System	13 Nov 2020 18:01:26

US3862110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:43:22
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 22:01:59

US3862110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	25 Nov 2020 22:01:59

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 64'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 71'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered 'Day 78'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 17:26:36

US3862110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:38:20
Data entry locked.	System	02 Sep 2020 17:26:36
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 17:26:36

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2020-11-27T06:37:05', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ccd76005-fe31-441c-bbb6-0d2c1eeb4e47'	System	27 Nov 2020 12:37:27
User entered 'No (N)'	System	27 Nov 2020 12:37:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2020-11-27T06:37:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ccd76005-fe31-441c-bbb6-0d2c1eeb4e47'	System	27 Nov 2020 12:37:27
User entered 'No (N)'	System	27 Nov 2020 12:37:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-11-27T06:37:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'ccd76005-fe31-441c-bbb6-0d2c1eeb4e47'	System	27 Nov 2020 12:37:27
User entered '27 Nov 2020 06:37:24'	System	27 Nov 2020 12:37:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2020-12-04T22:33:56', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e37b929e-c17e-4814-ae2e-b79c112ae4ac'	System	05 Dec 2020 04:34:17
User entered 'No (N)'	System	05 Dec 2020 04:34:17

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2020-12-04T22:34:06', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e37b929e-c17e-4814-ae2e-b79c112ae4ac'	System	05 Dec 2020 04:34:17
User entered 'No (N)'	System	05 Dec 2020 04:34:17

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-12-04T22:34:15', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'e37b929e-c17e-4814-ae2e-b79c112ae4ac'	System	05 Dec 2020 04:34:17
User entered '04 Dec 2020 22:34:15'	System	05 Dec 2020 04:34:17

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2020-12-11T11:28:35', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '991f2fb9-34ab-4207-97d2-28ad12f62d3d'	System	11 Dec 2020 17:28:48
User entered 'No (N)'	System	11 Dec 2020 17:28:48

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2020-12-11T11:28:39', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '991f2fb9-34ab-4207-97d2-28ad12f62d3d'	System	11 Dec 2020 17:28:48
User entered 'No (N)'	System	11 Dec 2020 17:28:48

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-12-11T11:28:45', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '991f2fb9-34ab-4207-97d2-28ad12f62d3d'	System	11 Dec 2020 17:28:48
User entered '11 Dec 2020 11:28:45'	System	11 Dec 2020 17:28:48

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2020-12-20T18:02:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '7465173b-ec17-4ae2-897b-f424131e2a8d'	System	21 Dec 2020 00:02:21
User entered 'No (N)'	System	21 Dec 2020 00:02:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2020-12-20T18:02:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '7465173b-ec17-4ae2-897b-f424131e2a8d'	System	21 Dec 2020 00:02:21
User entered 'No (N)'	System	21 Dec 2020 00:02:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-12-20T18:02:21', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '7465173b-ec17-4ae2-897b-f424131e2a8d'	System	21 Dec 2020 00:02:21
User entered '20 Dec 2020 18:02:21'	System	21 Dec 2020 00:02:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2020-12-26T01:35:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2ec186a3-798b-4f4b-864d-10eb95370fc4'	System	26 Dec 2020 07:36:11
User entered 'No (N)'	System	26 Dec 2020 07:36:11

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2020-12-26T01:36:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2ec186a3-798b-4f4b-864d-10eb95370fc4'	System	26 Dec 2020 07:36:11
User entered 'No (N)'	System	26 Dec 2020 07:36:11

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2020-12-26T01:36:09', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2ec186a3-798b-4f4b-864d-10eb95370fc4' User entered '26 Dec 2020 01:36:09'	System	26 Dec 2020 07:36:11
	System	26 Dec 2020 07:36:11

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-01T01:41:52', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd16e9298-5b45-49c3-85fb-f6e05125dff8'	System	01 Jan 2021 07:42:01
User entered 'No (N)'	System	01 Jan 2021 07:42:01

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-01-01T01:41:55', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd16e9298-5b45-49c3-85fb-f6e05125dff8'	System	01 Jan 2021 07:42:01
User entered 'No (N)'	System	01 Jan 2021 07:42:01

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-01-01T01:41:58', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd16e9298-5b45-49c3-85fb-f6e05125dff8'	System	01 Jan 2021 07:42:01
User entered '01 Jan 2021 01:41:58'	System	01 Jan 2021 07:42:01

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-08T05:34:07', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ec6bddf-038b-4d9e-907c-1b358538088b'	System	08 Jan 2021 11:34:22
User entered 'No (N)'	System	08 Jan 2021 11:34:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-01-08T05:34:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ec6bddf-038b-4d9e-907c-1b358538088b'	System	08 Jan 2021 11:34:22
User entered 'No (N)'	System	08 Jan 2021 11:34:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-01-08T05:34:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4ec6bddf-038b-4d9e-907c-1b358538088b' User entered '08 Jan 2021 05:34:19'	System	08 Jan 2021 11:34:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-15T01:11:14', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6786f18b-c1ff-424f-a91c-dfb3d6d13069'	System	15 Jan 2021 07:11:22
User entered 'No (N)'	System	15 Jan 2021 07:11:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-01-15T01:11:18', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6786f18b-c1ff-424f-a91c-dfb3d6d13069'	System	15 Jan 2021 07:11:22
User entered 'No (N)'	System	15 Jan 2021 07:11:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-01-15T01:11:22', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '6786f18b-c1ff-424f-a91c-dfb3d6d13069' User entered '15 Jan 2021 01:11:22'	System	15 Jan 2021 07:11:22
	System	15 Jan 2021 07:11:22

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-24T05:29:19', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered 'Yes (Y)'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-01-24T05:29:24', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered 'No (N)'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-24T05:29:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered 'No (N)'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-24T05:29:53', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered 'Yes (Y)'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please 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 (5cbc66fbda822862)', Time: '2021-01-24T05:30:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-01-24T05:30:16', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '90a15ea7-ef38-4ef8-b545-959276197393'	System	24 Jan 2021 11:30:26
User entered '24 Jan 2021 05:30:16'	System	24 Jan 2021 11:30:26

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-30T19:03:36', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered 'Yes (Y)'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-01-30T19:03:40', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered 'No (N)'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-30T19:03:47', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered 'No (N)'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-01-30T19:03:55', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered 'Yes (Y)'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please 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 (5cbc66fbda822862)', Time: '2021-01-30T19:03:59', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-01-30T19:04:03', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '019281df-e5cf-40b2-8d2e-5fd0f0e7b0a6'	System	31 Jan 2021 01:04:15
User entered '30 Jan 2021 19:04:03'	System	31 Jan 2021 01:04:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-02-07T11:58:46', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b22ec402-3bb1-402d-89d1-ef627a336853'	System	07 Feb 2021 17:59:14
User entered 'No (N)'	System	07 Feb 2021 17:59:14

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-02-07T11:59:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b22ec402-3bb1-402d-89d1-ef627a336853'	System	07 Feb 2021 17:59:14
User entered 'No (N)'	System	07 Feb 2021 17:59:14

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-02-07T11:59:10', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'b22ec402-3bb1-402d-89d1-ef627a336853'	System	07 Feb 2021 17:59:14
User entered '07 Feb 2021 11:59:10'	System	07 Feb 2021 17:59:14

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-02-12T07:04:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '01ef3c07-3b73-4535-8828-93f8f56bc77'	System	12 Feb 2021 13:04:21
User entered 'No (N)'	System	12 Feb 2021 13:04:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-02-12T07:04:17', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '01ef3c07-3b73-4535-8828-93f8f56bc77'	System	12 Feb 2021 13:04:21
User entered 'No (N)'	System	12 Feb 2021 13:04:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-02-12T07:04:21', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '01ef3c07-3b73-4535-8828-93f8f56bcb77'	System	12 Feb 2021 13:04:21
User entered '12 Feb 2021 07:04:21'	System	12 Feb 2021 13:04:21

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-02-22T09:27:04', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5def396b-9d05-4ae6-9766-11ef5d1199d7'	System	22 Feb 2021 15:27:15
User entered 'No (N)'	System	22 Feb 2021 15:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-02-22T09:27:08', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5def396b-9d05-4ae6-9766-11ef5d1199d7'	System	22 Feb 2021 15:27:15
User entered 'No (N)'	System	22 Feb 2021 15:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-02-22T09:27:12', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '5def396b-9d05-4ae6-9766-11ef5d1199d7'	System	22 Feb 2021 15:27:15
User entered '22 Feb 2021 09:27:12'	System	22 Feb 2021 15:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-02-26T21:51:42-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '088eb102-65d5-4fd0-8941-a533125a95a2'	System	27 Feb 2021 03:54:44
User entered 'No (N)'	System	27 Feb 2021 03:54:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-02-26T21:51:47-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '088eb102-65d5-4fd0-8941-a533125a95a2'	System	27 Feb 2021 03:54:44
User entered 'No (N)'	System	27 Feb 2021 03:54:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-02-26T21:51:57-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '088eb102-65d5-4fd0-8941-a533125a95a2'	System	27 Feb 2021 03:54:44
User entered '26 Feb 2021 21:51:57'	System	27 Feb 2021 03:54:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-03-07T14:54:14-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998'	System	07 Mar 2021 20:55:09
User entered 'Yes (Y)'	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-03-07T14:54:18-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998'	System	07 Mar 2021 20:55:09
User entered 'No (N)'	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-03-07T14:54:22-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998'	System	07 Mar 2021 20:55:09
User entered 'No (N)'	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-03-07T14:54:50-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998'	System	07 Mar 2021 20:55:09
User entered 'Yes (Y)'	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please 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 (5cbc66fbda822862)', Time: '2021-03-07T14:54:55-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998'	System	07 Mar 2021 20:55:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-03-07T14:55:01-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '28a64082-3e5d-49ee-954c-c6f54cd10998' User entered '07 Mar 2021 14:55:01'	System	07 Mar 2021 20:55:09
	System	07 Mar 2021 20:55:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-03-15T01:21:37-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0f85c513-e76e-4155-8686-733e737adc14'	System	15 Mar 2021 06:21:49
User entered 'No (N)'	System	15 Mar 2021 06:21:49

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-03-15T01:21:41-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0f85c513-e76e-4155-8686-733e737adc14'	System	15 Mar 2021 06:21:49
User entered 'No (N)'	System	15 Mar 2021 06:21:49

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-03-15T01:21:47-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '0f85c513-e76e-4155-8686-733e737adc14' User entered '15 Mar 2021 01:21:47'	System	15 Mar 2021 06:21:49
	System	15 Mar 2021 06:21:49

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (5cbc66fbda822862)', Time: '2021-03-21T16:01:10-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2b5a20b1-459d-474f-83e2-d992bdbab657'	System	21 Mar 2021 21:01:23
User entered 'No (N)'	System	21 Mar 2021 21:01:23

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (5cbc66fbda822862)', Time: '2021-03-21T16:01:16-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2b5a20b1-459d-474f-83e2-d992bdbab657'	System	21 Mar 2021 21:01:23
User entered 'No (N)'	System	21 Mar 2021 21:01:23

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-03-21T16:01:20-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '2b5a20b1-459d-474f-83e2-d992bdbab657'	System	21 Mar 2021 21:01:23
User entered '21 Mar 2021 16:01:20'	System	21 Mar 2021 21:01:23

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-02T22:01:25-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b'	System	03 Apr 2021 03:03:27
User entered 'Yes (Y)'	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (718216543c42c1df)', Time: '2021-04-02T22:01:30-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b'	System	03 Apr 2021 03:03:27
User entered 'No (N)'	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-02T22:01:34-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b' User entered 'No (N)'	System	03 Apr 2021 03:03:27
	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-02T22:01:39-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b' User entered 'Yes (Y)'	System	03 Apr 2021 03:03:27
	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Please 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 (718216543c42c1df)', Time: '2021-04-02T22:01:43-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b'	System	03 Apr 2021 03:03:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (718216543c42c1df)', Time: '2021-04-02T22:02:08-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '1e04ac27-0777-426b-9c94-0bc4a1486a1b'	System	03 Apr 2021 03:03:27
User entered '02 Apr 2021 22:02:08'	System	03 Apr 2021 03:03:27

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-09T08:05:34-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '820f8c8a-21b9-4f6e-bf00-9a6d01089a01'	System	09 Apr 2021 13:05:44
User entered 'No (N)'	System	09 Apr 2021 13:05:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (718216543c42c1df)', Time: '2021-04-09T08:05:39-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '820f8c8a-21b9-4f6e-bf00-9a6d01089a01'	System	09 Apr 2021 13:05:44
User entered 'No (N)'	System	09 Apr 2021 13:05:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (718216543c42c1df)', Time: '2021-04-09T08:05:43-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '820f8c8a-21b9-4f6e-bf00-9a6d01089a01'	System	09 Apr 2021 13:05:44
User entered '09 Apr 2021 08:05:43'	System	09 Apr 2021 13:05:44

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-17T20:03:35-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '572e7b12-51f1-4880-acf5-0963585b0b51'	System	18 Apr 2021 01:09:09
User entered 'No (N)'	System	18 Apr 2021 01:09:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (718216543c42c1df)', Time: '2021-04-17T20:03:39-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '572e7b12-51f1-4880-acf5-0963585b0b51'	System	18 Apr 2021 01:09:09
User entered 'No (N)'	System	18 Apr 2021 01:09:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (718216543c42c1df)', Time: '2021-04-17T20:03:44-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '572e7b12-51f1-4880-acf5-0963585b0b51' User entered '17 Apr 2021 20:03:44'	System	18 Apr 2021 01:09:09
	System	18 Apr 2021 01:09:09

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-23T07:27:07-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9a1edf29-2378-4e90-9132-b1fa3683aa7a' User entered 'No (N)'	System	23 Apr 2021 12:27:15
	System	23 Apr 2021 12:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (718216543c42c1df)', Time: '2021-04-23T07:27:09-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9a1edf29-2378-4e90-9132-b1fa3683aa7a' User entered 'No (N)'	System	23 Apr 2021 12:27:15
	System	23 Apr 2021 12:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (718216543c42c1df)', Time: '2021-04-23T07:27:12-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '9a1edf29-2378-4e90-9132-b1fa3683aa7a' User entered '23 Apr 2021 07:27:12'	System	23 Apr 2021 12:27:15
	System	23 Apr 2021 12:27:15

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[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 (718216543c42c1df)', Time: '2021-04-30T00:01:35-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4afc3ced-fa75-4ba5-912f-9c8f92017081' User entered 'No (N)'	System	30 Apr 2021 05:01:50
	System	30 Apr 2021 05:01:50

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

Have you been exposed to someone with 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 (718216543c42c1df)', Time: '2021-04-30T00:01:40-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4afc3ced-fa75-4ba5-912f-9c8f92017081' User entered 'No (N)'	System	30 Apr 2021 05:01:50
	System	30 Apr 2021 05:01:50

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (718216543c42c1df)', Time: '2021-04-30T00:01:44-05:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: '4afc3ced-fa75-4ba5-912f-9c8f92017081' User entered '30 Apr 2021 00:01:44'	System	30 Apr 2021 05:01:50
	System	30 Apr 2021 05:01:50

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:38:20

US3862110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:20
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:38:20

US3862110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:04:33

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)	24 Apr 2021 21:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-03-07T14:55:16-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd5a49a20-fa3b-4623-bb79-a83968f91077'	System	07 Mar 2021 20:55:26
User entered 'No (N)'	System	07 Mar 2021 20:55:26

US3862110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:04:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5cbc66fbda822862)', Time: '2021-03-07T14:55:23-06:00', User OID: 'PatientReportedOutcome (US3862110)', ODM File OID: 'd5a49a20-fa3b-4623-bb79-a83968f91077'	System	07 Mar 2021 20:55:26
User entered '07 Mar 2021 14:55:23'	System	07 Mar 2021 20:55:26

US3862110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 22:02:12

US3862110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:45
User entered '25 Nov 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 22:02:12

US3862110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	25 Nov 2020 22:02:12

US3862110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:45
User entered empty.	(b) (4) Sandra Francisco (b) (4)	25 Nov 2020 22:02:12

US3862110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:45
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	27 Nov 2020 23:05:43

US3862110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:54:36
User entered 'I'	System	27 Nov 2020 23:05:43

US3862110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	30 Dec 2020 18:16:32
	(b) (4)	

US3862110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '30 Dec 2020'	(b) (4) Thea Marie Cordero	30 Dec 2020 18:16:32
	(b) (4)	

US3862110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	30 Dec 2020 18:16:32
	(b) (4)	

US3862110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	30 Dec 2020 18:16:32
	(b) (4)	

US3862110

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	30 Dec 2020 18:16:39
	(b) (4)	

US3862110

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User entered 'I'	System	30 Dec 2020 18:16:39

US3862110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:39

US3862110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:39

US3862110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:39

US3862110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:39

US3862110

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	24 Mar 2021 20:54:34

US3862110

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User entered 'I'	System	24 Mar 2021 20:54:34

US3862110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:46

US3862110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:46

US3862110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:46

US3862110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:46

US3862110

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	25 Mar 2021 20:25:51

US3862110

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:46:10
User entered 'I'	System	25 Mar 2021 20:25:51

US3862110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:42:25
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '05 Apr 2021'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:42:25
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Clinic (Clinic)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:42:25
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'VISIT4'	System	05 Apr 2021 20:42:25

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '05 Apr 2021'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '10:22'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '05 Apr 2021 10:22'	System	05 Apr 2021 20:43:30

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '097.6' F	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Other (Other)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'TEMPORAL'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '076'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'bpm'	System	05 Apr 2021 20:43:30

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '015'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'breaths/min'	System	05 Apr 2021 20:43:30

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '124'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'mmHg'	System	05 Apr 2021 20:43:30

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '085'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:30
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'mmHg'	System	05 Apr 2021 20:43:30

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02

US3862110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02

US3862110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:45
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '05 Apr 2021'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:43:45
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:44:17
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '05 Apr 2021'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:44:17
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '10:43'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:44:17
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered '05 Apr 2021 10:43'	System	05 Apr 2021 20:44:17

US3862110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 20:44:23
	(b) (4)	

US3862110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:02
User entered 'I'	System	05 Apr 2021 20:44:23

US3862110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:12
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	28 Apr 2021 20:23:20
	(b) (4)	

US3862110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:12
	(b) (4)	
User entered '28 Apr 2021'	Thea Marie Cordero	28 Apr 2021 20:23:20
	(b) (4)	

US3862110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:12
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	28 Apr 2021 20:23:20
	(b) (4)	

US3862110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:12
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Apr 2021 20:23:20
	(b) (4)	

US3862110

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	29 Apr 2021 16:54:12
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	28 Apr 2021 20:23:25
	(b) (4)	

US3862110

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 20:23:25

US3862110

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:04:33

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:53:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 04:54:01
Query 'Data is required. Please complete.' answered with 'data entered in error ' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 22:02:22
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 22:02:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 22:02:18
User entered 'No (N)'		24 Mar 2021 17:08:15

US3862110

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

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:30

US3862110

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

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '22 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:30

US3862110

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

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[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 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:30

US3862110

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

Form: Visit Date

Generated On: 10 Jun 2021 10:04:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User entered 'UNBLND_DECIDE'	System	22 Feb 2021 22:31:30

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '22 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[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 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:00:50

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:00:50

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '22 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User entered empty.	System	22 Feb 2021 22:31:48

US3862110

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

Form: Unblinding

Generated On: 10 Jun 2021 10:04:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User entered empty.	System	22 Feb 2021 22:31:48

US3862110

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:18

US3862110

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 08:31:45
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'ACCESSION # 1F60F15' (Site from DM).	Thea Marie Cordero (b) (4)	24 Mar 2021 21:12:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:27:20
User entered '22 Feb 2021'	Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:18

US3862110

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '10:30'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:18

US3862110

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User entered '22 Feb 2021 10:30'	System	22 Feb 2021 22:35:18

US3862110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:25

US3862110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:33

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '22 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:25

US3862110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '10:27'	(b) (4) Carrie Kibler (b) (4) (b) (4)	22 Feb 2021 22:35:25

US3862110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:33

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:28:11
User entered '22 Feb 2021 10:27'	System	22 Feb 2021 22:35:25

US3862110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:04:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
DataPoint Verified.		13 Apr 2021 21:48:22
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, 152, and 187, 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		30 Mar 2021 12:39:37
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, 152, and 187, 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'DAY 145 : AE FOR HEADACHE, NAUSEA, VOMITING, UNCONTROLLED HYPERTENSION, DAY 152: FOLLOW-UP WITH CARDIOLOGIST FOR AE UNCONTROLLED HYPERTENSION, DAY 187: AE FOR MILD INTREMITTENT STUTTERING' (Site from DM).	Thea Marie Cordero (b) (4)	27 Mar 2021 01:39:58
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 145, 152, and 187, 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:00:49
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:16:01

US3862110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:04:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:25:51

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Mosquito bite - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 05:14:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 05:14:16
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 19:27:39
User entered 'Mosquito bites on bilateral arms and legs'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '2 Oct 2020'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 16:00:17
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:00:17
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 16:00:08
User entered 'Yes (Y)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '24 Oct 2020' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:00:08
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 30 Sept 2020 and AE#1 has a start date 02 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 09:30:02
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 30 Sept 2020 and AE#1 has a start date 02 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'Updated' (Site from DM).	Thea Marie Cordero (b) (4)	28 Oct 2020 15:59:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	28 Oct 2020 15:59:14
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 30 Sept 2020 and AE#1 has a start date 02 Oct 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:37:01
User entered 'None (NONE)'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '1'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Thea Marie Cordero	28 Oct 2020 16:00:08
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:26:56
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 19:26:56

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 20:27:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Dec 2020 20:27:58
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:27:19
User entered 'FATTY LIVER' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:27:02
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:24:16
Coding entries removed.	Thea Marie Cordero	15 Dec 2020 20:24:05
	(b) (4)	
User entered 'UNCONTROLLED OBESITY' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:24:05
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Abnormal weight gain, LLT: Unintentional weight gain - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 22:30:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 22:30:50
	(b) (4)	
Data point term sent to Coder	System	08 Dec 2020 22:30:29
User entered 'UNEXPLAINED WEIGHT GAIN'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '18 Nov 2020' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:27:02
	(b) (4)	
User entered '14 Dec 2020' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:24:05
	(b) (4)	
User entered '23 Nov 2020'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:27:02
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '1' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:27:02
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	15 Dec 2020 20:24:05
	(b) (4)	
User entered '1'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:27:02
	(b) (4)	
User entered '1' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 20:24:05
	(b) (4)	
User entered '0'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Dec 2020 22:29:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 22:29:42

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 20:42:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 20:42:54
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:28:20
User entered 'UNCONTROLLED OBESITY'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '14 Dec 2020'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:28:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 20:28:24
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero	15 Dec 2020 20:28:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 20:28:17
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '1'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:28:17
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 20:28:24

US3862110

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 20:28:17

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 20:30:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 20:30:59
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 20:30:21
User entered 'COLON POLYP'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '30 Nov 2020'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '30 Nov 2020'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered 'I'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:29:36
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 20:29:36

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM). Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'UNCONTROLLED HYPERTENSION IS THE CORRECT VERBIAGE FOR MEDICAL PROFESSIONALS. THE INDICATION IS CLEAR.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:26:00
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'UNCONTROLLED HYPERTENSION IS THE CORRECT VERBIAGE FOR MEDICAL PROFESSIONALS. THE INDICATION IS CLEAR.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	26 Feb 2021 23:53:05
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:30:45
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Uncontrolled hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:51:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:51:39
Data point term sent to Coder	System	02 Feb 2021 21:50:56
User entered 'UNCONTROLLED HYPERTENSION'	Thea Marie Cordero (b) (4)	02 Feb 2021 21:50:42

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:50:42

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	22 Feb 2021 23:07:54
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '01 Feb 2021' reason for change: Data Entry Error	Thea Marie Cordero	22 Feb 2021 23:07:54
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:50:42

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '1'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Thea Marie Cordero	22 Feb 2021 23:07:54
New Information	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:50:42
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 21:50:42

US3862110

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 21:50:42

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:53:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:53:36
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:52:57
User entered 'HEADACHE'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:52:35

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:52:35

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:52:35

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '1'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:52:35
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 21:52:35

US3862110

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 21:52:35

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:56:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:56:32
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:55:59
User entered 'NAUSEA'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:55:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:55:16
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero	02 Feb 2021 21:55:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:55:03
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Quer: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:14:55
User opened query 'Per CDM Re-Query: Site response noted. Please update the CM page when data is available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:14:53
Query 'Per CDM Re-Quer: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you.' answered with 'pending medical records' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:25:17
User opened query 'Per CDM Re-Quer: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:01:06
User closed query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:01:06
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
Query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' answered with 'STILL AWAITING MEDICAL RECORDS' (Site from DM).	(b) (4) Thea Marie Cordero	24 Mar 2021 19:14:03
User opened query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:20:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:19:00
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Awaiting medical records' (Site from DM).	Thea Marie Cordero (b) (4)	08 Mar 2021 18:27:42

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4) Thea Marie Cordero (b) (4)	26 Feb 2021 11:32:42 02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:55:03
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 21:55:16

US3862110

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 21:55:03

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:59:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 21:59:40
	(b) (4)	
Data point term sent to Coder	System	02 Feb 2021 21:59:03
User entered 'VOMITING'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:58:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 21:58:32
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero	02 Feb 2021 21:58:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 21:58:25
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:15:40
User opened query 'Per CDM Re-Query: Site response noted. Please update the CM page when data is available and then route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:15:38
Query 'Per CDM Re-Query: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you. ' answered with 'pending medical records ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:38:30
User opened query 'Per CDM Re-Query: Site response noted. Please u[date the CM page when data is available and then route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:01:41
User closed query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:01:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
Query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' answered with 'STILL AWAITING MEDICAL RECORDS' (Site from DM).	Thea Marie Cordero	24 Mar 2021 19:14:47
User opened query 'Per CDM RQ : site response noted, kindly update the data when it available. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:20:13
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:20:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'awaiting medical records' (Site from DM).	Thea Marie Cordero	08 Mar 2021 18:28:07

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4)	26 Feb 2021 11:33:13
	Thea Marie Cordero (b) (4)	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 21:58:25
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 21:58:32

US3862110

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Feb 2021 21:58:25

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Communication disorders and disturbances, HLT: Speech articulation and rhythm disturbances, PT: Dysphemia, LLT: Stuttering - version MedDRA\23.0.	Coder Import (b) (4)	09 Mar 2021 00:10:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Mar 2021 00:10:47
	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 18:30:50
User entered 'MILD INTERMITTENT STUTTERING'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered 'No (N)'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '26 Feb 2021'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered 'No (N)'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered '0'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '1'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered '0'	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:33
	(b) (4)	
User entered empty.	Thea Marie Cordero	08 Mar 2021 18:30:34
	(b) (4)	

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:33
User entered empty.	Thea Marie Cordero (b) (4)	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 18:30:34

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:50:47
Reviewed for Safety.		06 Apr 2021 14:06:11
User entered 'USA-US121-2021-mRNA-1273-P301000007'	System	06 Apr 2021 14:06:06
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 14:06:06

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:47
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:55:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:55:31
Data point term sent to Coder	System	05 Apr 2021 20:54:16
User entered 'CEREBROVASCULAR ACCIDENT'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:02
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 20:53:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 20:53:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:37
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 20:53:18
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:04
User entered 'No (N)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:06
User entered 'No (N)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:51
User entered '29 Mar 2021'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:53
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:11
User entered 'No (N)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:56
User entered '31 Mar 2021'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:13
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:16
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:19
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:21
User entered 'I'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	System	12 Apr 2021 21:34:13
	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:03
User entered '29 Mar 2021'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:05
User entered '31 Mar 2021'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:07
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	12 Apr 2021 21:34:13
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		12 Apr 2021 21:34:13
User entered empty; reason for change New Information	Thea Marie Cordero (b) (4)	12 Apr 2021 21:34:13
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	05 Apr 2021 20:53:18
User entered 'Unknown (UNK)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:22:09
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:35
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:32
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:33
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:37
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:39
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:40
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:51:44
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:13
User entered '0'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:52:42
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:39:23
User closed query 'Please move the comments here down one field to the "Narrative" section.' (Site from CRA).		19 Apr 2021 21:38:59
User entered 'LEFT SIDED HEMIPARESIS' reason for change: New Information	Thea Marie Cordero (b) (4)	16 Apr 2021 14:19:18
Query 'Please move the comments here down one field to the "Narrative" section.' answered with 'DONE' (Site from CRA).	Thea Marie Cordero (b) (4)	16 Apr 2021 14:17:38
User opened query 'Please move the comments here down one field to the "Narrative" section.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:27:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 19:26:46
DataPoint Verified.		14 Apr 2021 19:26:39
User entered '60 years old African American male Medical History: HTN, Type 2 DM, Obesity, Hyperlipidemia, HIV infection, BPH, Anxiety, GERD, Seasonal Allergies, Neuropathy, Medications: Farxiga, Topamax, Phentermine, Contrave, Nexium,Dovato, Loratadine, Repatha, Gabapentin, Bumetanide, Diltiazem, Lisinopril, Myrbetriq, Aspirin EUA Unblinding: 22 Feb 2021 Randomized treatment arm: mRNA 1273 First dose: 02 Sep 2020 Second dose: 30 Sep 2020 Subject came in 05 Apr 2021 for scheduled Visit 4 and reported the following: 1. 29 Mar 2021: Current mild stuttering (previously reported AE # 10) became progressively worst with “weakness”, “numbness” of left arm and left leg. Wife noticed left facial droop. Went to ER and was admitted on the same day. Had CT Scan and MRI of Brain: “No bleeding, no blood clot”. Subject was told he had a “stroke”. 2. 31 Mar 2021: Discharged home, prescribed with Aspirin 81 mg. Will undergo home Speech, Physical, Occupational therapy Subject with pronounced stuttering, residual left sided weakness and limping on ambulation. Will request medical records for details.' (non-conformant).	Thea Marie Cordero (b) (4)	05 Apr 2021 21:27:17

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	05 Apr 2021 21:24:31
User entered 'Subject with pronounced stuttering, residual left sided weakness and limping on ambulation.	Thea Marie Cordero (b) (4)	05 Apr 2021 21:24:31
Medical records will be requested for details' reason for change: Data Entry Error		
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	05 Apr 2021 20:53:18
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:39:11
User entered '60 YEARS OLD AFRICAN AMERICAN MALE MEDICAL HISTORY: HTN, TYPE 2 DM, OBESITY, HYPERLIPIDEMIA, HIV INFECTION, BPH, ANXIETY, GERD, SEASONAL ALLERGIES, NEUROPATHY, MEDICATIONS: FARXIGA, TOPAMAX, PHENTERMINE, CONTRAVE, NEXIUM,DOVATO, LORATADINE, REPATHA, GABAPENTIN, BUMETANIDE, DILTIAZEM, LISINOPRIL, MYRBETRIQ, ASPIRIN EUA UNBLINDING: 22 FEB 2021 RANDOMIZED TREATMENT ARM: MRNA 1273 FIRST DOSE: 02 SEP 2020 SECOND DOSE: 30 SEP 2020 SUBJECT CAME IN 05 APR 2021 FOR SCHEDULED VISIT 4 AND REPORTED THE FOLLOWING: 1. 29 MAR 2021: CURRENT MILD STUTTERING (PREVIOUSLY REPORTED AE # 10) BECAME PROGRESSIVELY WORST WITH "WEAKNESS", "NUMBNESS" OF LEFT ARM AND LEFT LEG. WIFE NOTICED LEFT FACIAL DROOP. WENT TO ER AND WAS ADMITTED ON THE SAME DAY. HAD CT SCAN AND MRI OF BRAIN: "NO BLEEDING, NO BLOOD CLOT". SUBJECT WAS TOLD HE HAD A "STROKE". 2. 31 MAR 2021: DISCHARGED HOME, PRESCRIBED WITH ASPIRIN 81 MG. WILL UNDERGO HOME SPEECH, PHYSICAL, OCCUPATIONAL THERAPY SUBJECT WITH PRONOUNCED STUTTERING, RESIDUAL LEFT SIDED WEAKNESS AND LIMPING ON AMBULATION. WILL REQUEST MEDICAL RECORDS FOR DETAILS.' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	16 Apr 2021 14:16:46

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:38:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	12 Apr 2021 21:34:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:04:23
User entered empty.	Thea Marie Cordero (b) (4)	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:53:37

US3862110

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 20:53:18

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Paralysis and paresis (excl cranial nerve), PT: Hemiparesis, LLT: Hemiparesis (left) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:15:01
Data point term sent to Coder	System	16 Apr 2021 14:34:40
User entered 'LEFT SIDED HEMIPARESIS'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:34:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 14:34:24
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:24
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:34:16
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:34:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 14:34:35
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:35
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 14:34:16
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	16 Apr 2021 14:34:16

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 14:34:35

US3862110

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:04:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 14:34:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:04:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Diary Dose 1 Day 3 indicates that Medication was taken for HEADACHE on 04SEP2020, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:30:23
Query 'Per DM CLR: Diary Dose 1 Day 3 indicates that Medication was taken for HEADACHE on 04SEP2020, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'UPDATED' (Site from DM).	Thea Marie Cordero (b) (4)	23 Feb 2021 00:05:12
User opened query 'Per DM CLR: Diary Dose 1 Day 3 indicates that Medication was taken for HEADACHE on 04SEP2020, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:36:40
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:01:35

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, PRODUCTSYNONYM: FARXIGA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:05:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:05:02
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 16:04:03
User entered 'FARXIGA' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 16:04:02
	(b) (4)	
User entered 'Faxiga'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:40:53
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'MH Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:56:09
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:22:18
User entered 'Diabetes Type II'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:03:48

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '10'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2016'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:03:48
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:03:48

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:03:48

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:03:48

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Nov 2020 21:01:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:01:36
Data point term sent to Coder Coding entries removed.	System Shetel Anassi (b) (4)	09 Nov 2020 21:01:09 09 Nov 2020 21:00:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:07:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:07:45
Data point term sent to Coder User entered 'Trulicity'	System Trent Davis (b) (4)	03 Sep 2020 16:07:06 03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per CDM Re-Query: Site response noted; however, the data has not been updated into the Medical History form. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:53:08
Query 'Per CDM Re-Query: Site response noted; however, the data has not been updated into the Medical History form. Please review and reconcile. Thank you. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	13 Nov 2020 22:56:36
User opened query 'Per CDM Re-Query: Site response noted; however, the data has not been updated into the Medical History form. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:29:22
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:29:22
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:56:19
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:23:02
User entered 'Diabetes Type II'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 07:26:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:23:47
User entered '1.5/.5'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Other (OTHER)'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg/ml'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'every week (QS)'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:27:23
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:00:51
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:00:44
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:23:33
User entered 'Intramuscular (INTRAMUSCULAR)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per CDM: Please review and reconcile with MH eCRF so that there is an appropriate match. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please review and reconcile with MH eCRF so that there is an appropriate match. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:23:00
User entered 'UN UNK 2014' reason for change: New Information	Thea Marie Cordero (b) (4)	15 Dec 2020 19:10:06
User opened query 'Per CDM: Please review and reconcile with MH eCRF so that there is an appropriate match. Thank you.' (Site from DM).	Thea Marie Cordero (b) (4)	15 Dec 2020 19:09:59
User entered 'un UNK 2017'	(b) (4), (b) (6)	24 Nov 2020 06:54:35
	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:07:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	03 Sep 2020 16:07:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:11:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:11:51
Data point term sent to Coder User entered 'Lisinopril'	System Trent Davis (b) (4)	03 Sep 2020 16:11:21 03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Hypertension'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '10'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'un UNK 2014' reason for change:	(b) (4)	
Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:06:41
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:11:01
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0' reason for change: Data Entry Error	(b) (4) Thea Marie Cordero	28 Oct 2020 16:06:41
User entered '1'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)' reason for change: New Information	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:39
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '26 Jan 2021' reason for change: New Information	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:39
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User entered '1'	System	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User entered '1'	System	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:36
User entered '804 (804)'	System	03 Sep 2020 16:11:01

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 23:06:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 23:06:00
Data point term sent to Coder Coding entries removed.	System Thea Marie Cordero	22 Feb 2021 23:05:30 22 Feb 2021 23:05:17
User entered 'CLONIDINE' reason for change: New Information	(b) (4) Thea Marie Cordero	22 Feb 2021 23:05:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:18:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:18:50
Data point term sent to Coder User entered 'Carvedilol'	System Trent Davis (b) (4)	03 Sep 2020 16:15:32 03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Hypertension'	Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:34:15
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Thea Marie Cordero (b) (4)	22 Feb 2021 23:05:22
User entered '0.1' reason for change: New Information	Thea Marie Cordero (b) (4)	22 Feb 2021 23:05:17
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:58:12
User entered '0.01'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'every week (QS)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:36:32
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'update not needed. transdermal administration is was reported' (Site from DM).	Sandra Francisco (b) (4)	20 Feb 2021 00:00:05
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:58:28
User entered 'Transdermal (TRANSDERMAL)'	Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'un UNK 2019'	Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 16:10:26
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	03 Sep 2020 16:15:19
	Trent Davis (b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 16:10:26
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:10:26
	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 16:15:19
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User entered '1'	System	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User entered '1'	System	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:40
User entered '803 (803)'	System	03 Sep 2020 16:15:19

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:47:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:47:42
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 16:23:42
User entered 'Mybetriq'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Benign prostatic hyperplasia'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '50'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2018'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:22:45
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:22:45

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:22:45

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:22:45

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:49:45
Reviewed for Data Management.	(b) (4)	17 Nov 2020 20:49:32
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: OTHER EMOLLIENTS AND PROTECTIVES, PRODUCT: AMMONIUM LACTATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:43:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:43:39
Data point term sent to Coder	System	09 Nov 2020 20:59:01
Data point term sent to Coder	System	09 Nov 2020 20:58:00
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:57:28
User entered 'AMMONIA LACTATE 12%' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:57:28
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: OTHER EMOLLIENTS AND PROTECTIVES, PRODUCT: AMMONIUM LACTATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:58:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:58:42
Data point term sent to Coder	System	03 Sep 2020 16:41:29
User entered 'ammonia lactate'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:40:43

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Dry Skin'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per CDM: Requery: Response noted, however this is not the actual dose. Please update dose and dose unit in application (e.g. 1 application etc.).Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 08:41:00
Query 'Per CDM: Requery: Response noted, however this is not the actual dose. Please update dose and dose unit in application (e.g. 1 application etc.).Thank you.' answered with 'updated: EDC and source documents match' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 21:45:46
User entered '1' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	25 Nov 2020 21:44:18
User opened query 'Per CDM: Requery: Response noted, however this is not the actual dose. Please update dose and dose unit in application (e.g. 1 application etc.).Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:50:47
User closed query 'Per CDM re-query: Site response noted, however, please update the dose and dose unit with the actual dose administered (eg, 1 application, etc). Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:41:41
Query 'Per CDM re-query: Site response noted, however, please update the dose and dose unit with the actual dose administered (eg, 1 application, etc). Thank you. ' answered with 'Information is correct per directions of medication. Dose 12% as PRN.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 21:23:22
User opened query 'Per CDM re-query: Site response noted, however, please update the dose and dose unit with the actual dose administered (eg, 1 application, etc). Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:56:15
User closed query 'Per DM CLR: Note, 12% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:56:15

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Note, 12% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' answered with 'updated' (Site from DM).	Shetel Anassi (b) (4)	09 Nov 2020 20:57:35
User entered 'pea size amount' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 20:57:28
User opened query 'Per DM CLR: Note, 12% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:29:12
User entered '12'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Other (OTHER)'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'application' reason for change: Per Query Resolution	Sandra Francisco (b) (4)	25 Nov 2020 21:44:18
	(b) (4)	
User entered 'percent'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'twice daily (BID)'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:30:08
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:58:35
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:58:28
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:28:54
User entered 'Subcutaneous (SUBCUTANEOUS)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:40:43

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2018'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:40:43
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 16:40:43

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:40:43

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:40:43

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:10:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 03:10:33
Data point term sent to Coder	System	03 Sep 2020 16:42:31
User entered 'Topamax'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:42:07

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Anxiety'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '50'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'twice daily (BID)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2020'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:42:07
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Sep 2020 16:42:07

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:42:07

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:42:07

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 16:45:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:45:46
Data point term sent to Coder	System	03 Sep 2020 16:44:34
User entered 'PHENTERMINE' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 16:43:53
Data point term sent to Coder	System	03 Sep 2020 16:43:33
User entered 'Fhentermine'	Trent Davis (b) (4)	03 Sep 2020 16:43:10

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Obesity'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '37.5'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 16:43:43
User entered 'un UNK 2020' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 16:43:43
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Sep 2020 16:43:10
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:43:10
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:43:10

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:43:10

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:43:10

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
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: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4)	15 Sep 2020 19:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	15 Sep 2020 19:14:52
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: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	03 Sep 2020 16:49:46
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	03 Sep 2020 16:49:46
Data point term sent to Coders	System	03 Sep 2020 16:48:39
User entered 'NEXIUM' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:48:32
User entered 'Nexum'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 16:47:51

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '40'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2016'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 16:47:51
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:47:51

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 16:47:51

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 16:47:51

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
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: ERGOCALCIFEROL, PRODUCTSYNONYM: DRISDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:40:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:40:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 17:39:14
Data point term sent to Coder	System	03 Sep 2020 17:38:11
User entered 'Drisdol'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:38:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 17:38:19
User entered 'Vitamin D Deficiency' reason for change: Data Entry Error	Trent Davis (b) (4)	03 Sep 2020 17:38:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 17:37:56
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '1.25'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
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) (4), (b) (6)	12 Nov 2020 13:30:34
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:59:36
User entered 'mg (mg)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:59:29
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)	08 Nov 2020 07:32:16
User entered 'mL (mL)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:37:56

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2018' reason for change:	Thea Marie Cordero	28 Oct 2020 16:07:23
Data Entry Error	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:07:23
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:37:56
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:37:56

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:37:56

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 17:37:56

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:42:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:42:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 17:42:17
User entered 'Loratadine'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Seasonal Allergies'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '10'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2018' reason for change:	Thea Marie Cordero	28 Oct 2020 16:08:03
Data Entry Error	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero	28 Oct 2020 16:08:03
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:41:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:41:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:41:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 17:41:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: DOVATO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:52:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:52:46
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 17:51:42
User entered 'Dovato'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'human immunodeficiency virus'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'tablet (TABLET)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2020'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:51:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:51:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:51:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 17:51:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 19:08:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 19:08:02
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	15 Dec 2020 19:07:00
	Thea Marie Cordero	15 Dec 2020 19:06:07
	(b) (4)	
User entered 'REPATHA' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 19:06:07
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:19:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:19:32
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	09 Nov 2020 21:02:10
	Shetel Anassi (b) (4)	09 Nov 2020 21:01:35
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB, PRODUCTSYNONYM: REPATHA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 08:50:36
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Repathe'	Coder Import (b) (4) (b) (4) System Trent Davis (b) (4) (b) (4)	09 Sep 2020 08:50:36 03 Sep 2020 17:55:55 03 Sep 2020 17:55:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'hypercholesterolemia'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '140'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'other (OTHER)'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'every two weeks'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:30:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:01:40
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:01:35
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:30:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:55:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2017'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:55:16
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:55:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:55:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:55:16

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 12:33:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 12:33:52
	(b) (4)	
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)	09 Nov 2020 21:04:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 21:04:37
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 21:03:12
Coding entries removed.	Shetel Anassi (b) (4)	09 Nov 2020 21:02:29
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:57:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 17:57:47
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 17:56:58
User entered 'Gabapentin'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:30:55
Query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:02:47
User entered 'SENSORY NEUROPATHY IN BOTH FEET' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 21:02:29
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the NEUROPATHY (i.e. sensory or motor; Bilateral, left, Right; Arm or legs). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 07:31:45
User entered 'Neuropathy'	Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:55:59

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '300'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'three times daily (TID)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'un UNK 2010'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 17:55:59
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 Sep 2020 17:55:59

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:55:59

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 17:55:59

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 17:59:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:59:42
Data point term sent to Coder User entered 'furosemide'	System Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:59:03 03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Hypertension'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '40'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'un UNK 2010'	Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 16:10:59
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	03 Sep 2020 17:58:11
	Trent Davis (b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 16:10:59
User entered empty.	Thea Marie Cordero (b) (4)	03 Sep 2020 17:58:11
	Trent Davis (b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User entered '1'	System	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User entered '1'	System	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:08:45
User entered '804 (804)'	System	03 Sep 2020 17:58:11

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: NEOSPORIN [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Oct 2020 12:20:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 12:20:27
Data point term sent to Coder	System	07 Oct 2020 19:38:06
User entered 'NEOSPORIN OINTMENT (BACITRACIN 400 UNITS ,NEOMYCIN 3.5 MG, POLYMYXIN B 5,000 UNITS PER 1 GRAM)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	07 Oct 2020 19:37:33
Data point term sent to Coder	System	07 Oct 2020 19:36:03
User entered 'Neosporin ointment'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Mosquito bites on bilateral arms and legs'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response as the dose and unit is already provided in the name of medication field (e.g. Dose = 2, Unit = Other: Application). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:23:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response as the dose and unit is already provided in the name of medication field (e.g. Dose = 2, Unit = Other: Application). Update as appropriate, otherwise clarify. ' answered with 'data entered per query solution ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:58
User entered '2' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Mar 2021 19:55:27
User entered '3' reason for change: Per Query Resolution		23 Mar 2021 19:54:17
User opened query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response as the dose and unit is already provided in the name of medication field (e.g. Dose = 2, Unit = Other: Application). Update as appropriate, otherwise clarify. ' (Site from DM).		25 Feb 2021 19:24:09
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)	04 Feb 2021 17:02:31
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).	Thea Marie Cordero (b) (4)	02 Feb 2021 22:13:27
User entered '400S/3.5/5000' reason for change: New Information	Thea Marie Cordero (b) (4)	02 Feb 2021 22:13:20
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)	02 Feb 2021 06:48:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and verify if the dose and unit can be more appropriately recorded as number of application for this topical medication. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:23:20
Query 'Per DM CLR: Please review and verify if the dose and unit can be more appropriately recorded as number of application for this topical medication. If yes, please update accordingly.'	Thea Marie Cordero	15 Dec 2020 19:02:56
' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered '400UNITS/3.5MG/5000UNITS' reason for change: New Information	Thea Marie Cordero	15 Dec 2020 19:02:49
User opened query 'Per DM CLR: Please review and verify if the dose and unit can be more appropriately recorded as number of application for this topical medication. If yes, please update accordingly.'	(b) (4), (b) (6)	03 Dec 2020 18:40:24
' (Site from DM).		
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 19:37:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 19:37:33
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	07 Oct 2020 19:37:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	07 Oct 2020 19:35:37
	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	15 Dec 2020 19:02:49
User entered 'g (g)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	07 Oct 2020 19:37:33
User entered 'Other (OTHER)'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'application' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:17
User entered '1 THIN LAYER' reason for change: New Information	Thea Marie Cordero (b) (4)	15 Dec 2020 19:02:49
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	07 Oct 2020 19:37:33
User entered 'Bacitracin 400 units ,Neomycin 3.5 mg, Polymyxin B 5,000 units per 1 gram'	Thea Marie Cordero (b) (4)	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Topical (TOPICAL)'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '2 Oct 2020'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '3 Oct 2020'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	07 Oct 2020 19:35:37
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 19:35:37

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:39
Data point term sent to Coder	System	28 Oct 2020 16:10:19
User entered 'Influenza vaccine high dose'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:09:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Influenza prevention'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0.5'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mL (mL)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '26 Oct 2020'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '26 Oct 2020'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	28 Oct 2020 16:09:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User entered empty.	System	28 Oct 2020 16:09:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User entered empty.	System	28 Oct 2020 16:09:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:27
User entered empty.	System	28 Oct 2020 16:09:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:39:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:39:32
Data point term sent to Coder	System	28 Oct 2020 16:12:21
User entered 'Bumetanide'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:11:55

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Hypertension'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '2'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:37:01
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'BUMETANIDE WAS ADDED AS SUBJECT'S CONCOMITANT MEDICATION BECAUSE CLONIDINE WAS DISCONTINUED' (Site from DM).	Thea Marie Cordero (b) (4)	22 Feb 2021 23:15:07
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:01:14
User entered '24 Oct 2020'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:11:55

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	28 Oct 2020 16:11:55
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:11:55

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:11:55

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 16:11:55

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:39:58
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Oct 2020 18:39:58
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 16:13:23
User entered 'Diltiazem ER'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:13:17

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Hypertension'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '240'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once daily (QD)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:37:11
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'DILTIAZEM ER WAS ADDED AS SUBJECT'S CONCOMITANT MEDICATION BECAUSE CLONIDINE WAS DISCONTINUED' (Site from DM).	Thea Marie Cordero (b) (4)	22 Feb 2021 23:16:57
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:01:36
User entered '24 Oct 2020'	Thea Marie Cordero (b) (4)	28 Oct 2020 16:13:17

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	28 Oct 2020 16:13:17
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:13:17

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:13:17

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 16:13:17

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Per DM CLR: this Con Med had dose increased on 27 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 09:39:47
Query 'Per DM CLR: this Con Med had dose increased on 27 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'UNCONTROLLED HYPERTENSION IS THE CORRECT VERBIAGE FOR MEDICAL PROFESSIONALS. THE INDICATION IS CLEAR.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	26 Feb 2021 23:54:41
User opened query 'Per DM CLR: this Con Med had dose increased on 27 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:24:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:23:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:23:36
Data point term sent to Coder	System	02 Feb 2021 22:04:06
User entered 'LISINOPRIL'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:04:00

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'UNCONTROLLED HYPERTENSION'	(b) (4) Thea Marie Cordero (b) (4)	02 Feb 2021 22:04:00

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '20'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '27 Jan 2021'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:04:00
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User entered '1'	System	02 Feb 2021 22:04:00

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User entered '1'	System	02 Feb 2021 22:04:00

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:09:19
User entered '804 (804)'	System	02 Feb 2021 22:04:00

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: BUPROPION HYDROCHLORIDE;NALTREXONE HYDROCHLORIDE, PRODUCTSYNONYM: CONTRAVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 00:05:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	03 Feb 2021 00:05:33
Data point term sent to Coder	System	02 Feb 2021 22:23:33
User entered 'CONTRAVE (NALTREXONE 8 MG BUPROPION HCL 90 MG)'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:23:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'UNCONTROLLED OBESITY'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '8/90'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '14 Dec 2020'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '20 Dec 2020'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:23:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User entered '1'	System	02 Feb 2021 22:23:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User entered '1'	System	02 Feb 2021 22:23:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:38
User entered '804 (804)'	System	02 Feb 2021 22:23:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMINARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: BUPROPION HYDROCHLORIDE;NALTREXONE HYDROCHLORIDE, PRODUCTSYNONYM: CONTRAVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 00:05:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	03 Feb 2021 00:05:34
Data point term sent to Coder	System	02 Feb 2021 22:25:43
User entered 'CONTRAVE (NALTREXONE 8 MG BUPROPION HCL 90 MG)'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'UNCONTROLLED OBESITY'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '8/90'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'twice daily (BID)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with CONTRAVE (NALTREXONE 8 MG BUPROPION 90 MG) CM#27 / (Start date 4 JAN 2021 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).		26 Apr 2021 08:42:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with CONTRAVE (NALTREXONE 8 MG BUPROPION 90 MG) CM#27 / (Start date 4 JAN 2021 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'RECORDED ERRONEOUSLY. CORRECTION DONE AS REFELCTED IN SOURCE DOCUMENT' (Site from DM).	Thea Marie Cordero (b) (4)	24 Mar 2021 21:25:36
User entered '21 Dec 2020' reason for change: New Information	Thea Marie Cordero (b) (4)	24 Mar 2021 21:24:47
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with CONTRAVE (NALTREXONE 8 MG BUPROPION 90 MG) CM#27 / (Start date 4 JAN 2021 - Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:26:22
User entered '21 Jan 2021'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '27 Dec 2020' reason for change: New Information	(b) (4) Thea Marie Cordero	24 Mar 2021 21:24:47
User entered '27 Jan 2021'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:24:46
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User entered '2'	System	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User entered '1'	System	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:42
User entered '804 (804)'	System	02 Feb 2021 22:24:46

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 09:06:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 09:06:41
Data point term sent to Coder	System	02 Feb 2021 22:28:45
User entered 'MORPHINE'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:28:38

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'HEADACHE'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-Query: Site response noted. Please update when available and route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:53:22
User closed query 'Per CDM: Please update the 'Dose per administration' and Dose unit' of the Concomitant medication. Thankyou.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:53:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Query 'Per CDM: Please update the 'Dose per administration' and Dose unit' of the Concomitant medication. Thankyou.' answered with 'AWAITING MEDICAL RECORDS' (Site from DM).	(b) (4) Thea Marie Cordero	24 Mar 2021 19:17:53
User opened query 'Per CDM: Please update the 'Dose per administration' and Dose unit' of the Concomitant medication. Thankyou.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:38:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 12:37:40
Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System).	Sandra Francisco (b) (4)	20 Feb 2021 00:17:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 22:28:38
User entered empty.	System	02 Feb 2021 22:28:38
	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:37:42
Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System).	Sandra Francisco (b) (4) (b) (4)	20 Feb 2021 00:17:38
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 22:28:38
User entered empty.	Thea Marie Cordero (b) (4)	02 Feb 2021 22:28:38

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'once (ONCE)'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:28:38
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:28:38

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:28:38

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:28:38

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:01:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 01:01:38
Data point term sent to Coder	System	02 Feb 2021 22:29:46
User entered 'HYDRALAZINE'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:29:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'UNCONTROLLED HYPERTENSION'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-Query: Site response noted. Please update when available and route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:53:35
User closed query 'Per CDM: Please update the 'Dose per administration' , "Dose unit" and "frequency" of the Concomitant medication. Thankyou. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:53:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Query 'Per CDM: Please update the 'Dose per administration' , "Dose unit" and "frequency" of the Concomitant medication. Thankyou. ' answered with 'AWAITING MEDICAL RECORDS' (Site from DM).	(b) (4) Thea Marie Cordero	24 Mar 2021 19:18:24
User opened query 'Per CDM: Please update the 'Dose per administration' , "Dose unit" and "frequency" of the Concomitant medication. Thankyou. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:40:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 12:38:52
Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System).	Sandra Francisco (b) (4)	20 Feb 2021 00:17:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 22:29:30
User entered empty.	System	02 Feb 2021 22:29:30
	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 12:38:54
User opened query 'Data is required. Please complete.' (Site from System).	Sandra Francisco (b) (4)	20 Feb 2021 00:17:45
User entered empty.	(b) (4)	
	System	02 Feb 2021 22:29:30
	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'pending medical records' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 12:38:56
User opened query 'Data is required. Please complete.' (Site from System).	Sandra Francisco (b) (4)	20 Feb 2021 00:17:49
User entered empty.	(b) (4)	
	System	02 Feb 2021 22:29:30
	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '19 Jan 2021'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:29:30
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:29:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:29:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:29:30

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: BUPROPION HYDROCHLORIDE;NALTREXONE HYDROCHLORIDE, PRODUCTSYNONYM: CONTRAVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 00:05:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	03 Feb 2021 00:05:34
Data point term sent to Coder	System	02 Feb 2021 22:32:49
User entered 'CONTRAVE (NALTREXONE 8MG BUPROPION HCL 90 MG)'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:32:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'UNCONTROLLED OBESITY'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '8/90'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '2 TABLETS IN AM 1 TABLET IN PM'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '28 Dec 2020'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '03 Jan 2021' reason for change: Data Entry Error	(b) (4)	20 Feb 2021 00:17:58
User entered '3 Jan 2021'	Sandra Francisco (b) (4)	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	02 Feb 2021 22:32:18
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User entered empty.	System	02 Feb 2021 22:32:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User entered empty.	System	02 Feb 2021 22:32:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:46
User entered empty.	System	02 Feb 2021 22:32:18

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: BUPROPION HYDROCHLORIDE;NALTREXONE HYDROCHLORIDE, PRODUCTSYNONYM: CONTRAVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Feb 2021 00:04:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 00:04:39
Data point term sent to Coder	System	02 Feb 2021 22:34:51
User entered 'CONTRAVE (NALTREXONE 8 MG BUPROPION 90 MG)'	Thea Marie Cordero (b) (4)	02 Feb 2021 22:34:49

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'UNCONTROLLED OBESITY'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '8/90'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'other (OTHER)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '2 TABLETS TWO TIMES A DAY'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '4 Jan 2021'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	02 Feb 2021 22:34:49
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:34:49

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:34:49

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 22:34:49

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CYNARA CARDUNCULUS;MALUS SPP. VINEGAR EXTRACT;TARAXACUM OFFICINALE, PRODUCTSYNONYM: APPLE CIDER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 22:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 22:15:57
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CYNARA CARDUNCULUS;MALUS SPP. VINEGAR EXTRACT;TARAXACUM OFFICINALE, PRODUCTSYNONYM: APPLE CIDER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Apr 2021 19:46:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Apr 2021 19:46:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
Data point term sent to Coder	System	22 Feb 2021 23:10:43
User entered 'APPLE CIDER GUMMIES'	Thea Marie Cordero (b) (4)	22 Feb 2021 23:09:47

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'GENERAL WELL BEING'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '1200'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'three times daily (TID)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '15 Feb 2021'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '0'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	22 Feb 2021 23:09:47
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Feb 2021 23:09:47

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 23:09:47

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 23:09:47

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 00:12:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 00:12:57
Data point term sent to Coder	System	23 Feb 2021 00:12:42
User entered 'TYLENOL'	Thea Marie Cordero (b) (4)	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE did not meet the AE reporting criteria. ' (Site from DM).		26 Apr 2021 08:48:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:21:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE did not meet the AE reporting criteria. ' answered with 'POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE: CONSIDERED EXPECTED SYSTEMIC ADVERSE REACTION. DOES NOT MEET AE CRITERIA' (Site from DM).	Thea Marie Cordero (b) (4)	24 Mar 2021 21:16:57

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 15:31:03
User entered 'POST VACCINATION REACTOGENICITY SYMPTOM: HEADACHE'	Thea Marie Cordero (b) (4)	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '1000'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '04 Sep 2020'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '0'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'No (N)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '04 Sep 2020'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User entered empty.	System	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User entered empty.	System	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:52
User entered empty.	System	23 Feb 2021 00:12:03

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
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)	06 Apr 2021 04:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:31:42
Data point term sent to Coder	System	05 Apr 2021 21:40:14
User entered 'ASPIRIN'	Thea Marie Cordero (b) (4)	05 Apr 2021 21:39:58

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'THROMBOEMBOLITIC STROKE PREVENTION'	(b) (4) Thea Marie Cordero (b) (4)	05 Apr 2021 21:39:58

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '81'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered empty.	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered empty.	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered empty.	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '01 Apr 2021'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '0'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered empty.	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:32:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'No (N)'	(b) (4) Thea Marie Cordero	05 Apr 2021 21:39:58
	(b) (4)	

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:39:58

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:39:58

US3862110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:04:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 21:39:58

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:04:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	15 Dec 2020 20:29:55
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered '18 Nov 2020'	Thea Marie Cordero	15 Dec 2020 20:30:31
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'CT SCAN OF ABDOMEN AND PELVIS'	Thea Marie Cordero	15 Dec 2020 20:30:31
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered 'Adverse Event (AE)'	Thea Marie Cordero	15 Dec 2020 20:30:31
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:04:33

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	15 Dec 2020 20:30:31
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered '30 Nov 2020'	(b) (4) Thea Marie Cordero	15 Dec 2020 20:31:06
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'COLONOSCOPY'	(b) (4) Thea Marie Cordero	15 Dec 2020 20:31:06
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered 'Adverse Event (AE)'	(b) (4) Thea Marie Cordero	15 Dec 2020 20:31:06
	(b) (4)	

US3862110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:04:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:21:58
User entered empty.	(b) (4) Thea Marie Cordero	15 Dec 2020 20:31:06
	(b) (4)	

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'USA-US121-2021-MRNA-1273-P301000007'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Thea Marie'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Cordero'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Houston'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'TX'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered '77030'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
Reviewed for Safety.		13 Apr 2021 16:39:07
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'US'	(b) (4) System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 12:54:06
User entered '2'	System	13 Apr 2021 16:39:37
User entered '1'	System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'USA-US121-2021-MRNA-1273-P301000007'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Thea Marie'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Cordero'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Houston'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'TX'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered '77030'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
Reviewed for Safety.		13 Apr 2021 16:39:07
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'US'	(b) (4) System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 12:54:06
User entered '2'	System	13 Apr 2021 16:39:37
User entered '1'	System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:04:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered '06/Apr/2021 10:06'	(b) (4) System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:04:33

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
Reviewed for Safety.		13 Apr 2021 16:39:07
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'USA-US121-2021-MRNA-1273-P301000007'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Thea Marie'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Cordero'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Houston'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'TX'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered '77030'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
Reviewed for Safety.		13 Apr 2021 16:39:07
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'US'	(b) (4) System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 12:54:06
User entered '2'	System	13 Apr 2021 16:39:37
User entered '1'	System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:04:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:47:18
User entered '13/Apr/2021 12:39'	System	13 Apr 2021 16:39:37

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:04:33

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 12:53:54
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 16:39:37

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'USA-US121-2021-MRNA-1273-P301000007'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Yes (Y)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'No (N)'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Thea Marie'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Cordero'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'Houston'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered 'TX'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 14:06:31
User entered '77030'	System	06 Apr 2021 14:06:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:47:18
Reviewed for Safety.		13 Apr 2021 16:39:07
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:00
User entered 'US'	(b) (4) System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 12:54:06
User entered '2'	System	13 Apr 2021 16:39:37
User entered '1'	System	06 Apr 2021 14:06:45

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:04:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:05
	(b) (4)	
User entered '19/Apr/2021 07:54'	System	19 Apr 2021 12:54:06

US3862110

Folder: SAE USA-US121-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:04:33

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.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 12:54:06