

US3842027 (Prod: New Jersey Medical School)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:02:02

All time stamps listed in this document are displayed in GMT

US3842027

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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[Participant ID](#)

US3842027

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

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US3842027

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3842027

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 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

US3842027

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	LEFT PNEUMOTHORAX
Start date (dd MMM yyyy)	03 MAY 2020
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)	09 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	TYPE II DIABETES (INSULIN DEPENDENT)
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 (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2008
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 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	LUNG CANCER
Start date (dd MMM yyyy)	UN UNK 2013
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 UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	COLON CANCER
Start date (dd MMM yyyy)	UN UNK 2012
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 UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	HEART VALVE TAVR REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2016
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 UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	SLEEP APNEIA
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 (8)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	CATARACT SURGERY
Start date (dd MMM yyyy)	UN UNK 2019
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 UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	TREMORS, HANDS
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 (10)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	ELEVATED BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	COPD (CHRONIC OBSTRUCTIVE PULMONARY DISEASE)
Start date (dd MMM yyyy)	UN MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	"BENIGN PROSTATIC HYPERPLASIA,
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	ASTHMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	DISTANT LUNG LYMPHADENOPATHY BENIGN
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	ILEOSTOMY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	CHRONIC BILATERAL LOWER EXTREMITY EDEMA (SECONDARY TO VENOUS INSUFFICIENCY)
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	BENIGN PROSTATE HYPERPLASIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Condition	CONSTIPATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:30 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:30
Height ( <i>xxx.x</i> )	174.2 cm
Weight ( <i>xxx.x</i> )	110 kg
BMI ( <i>xxx.x</i> )	36.24903 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842027

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 189399

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) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

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) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

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)	10 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:30
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

Height	ND - Not Done
Weight	ND - Not Done
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)	10 SEP 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:45
Temperature (xxx.x)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	151 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 13:09

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) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	10 SEP 2020
Collection time ( <i>00:00-23:59</i> )	12:00 (24 HR)
Collection date and time (derived)	10 SEP 2020 12:00



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:10	10 SEP 2020 12:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

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 10:02:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.5 °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

10 SEP 2020 13:57

PC Open Date & Time

10 SEP 2020 13:29

PC Close Date & Time

10 SEP 2020 15:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**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.

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 10 SEP 2020 16:54

PC Close Date & Time 11 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 09:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**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

97.7 °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

15 SEP 2020 14:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**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

97.7 °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

16 SEP 2020 15:23

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**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

10 SEP 2020 13:57

PC Open Date & Time

10 SEP 2020 13:29

PC Close Date & Time

10 SEP 2020 15:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 16:54

PC Close Date & Time

11 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

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

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**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

14 SEP 2020 09:31

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

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

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**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

15 SEP 2020 14:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**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

16 SEP 2020 15:24

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:57
PC Open Date & Time	10 SEP 2020 13:29
PC Close Date & Time	10 SEP 2020 15:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 16:54

PC Close Date & Time

11 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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 ☐

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

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EAB) (1725)

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US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Yes ☐

PC Time stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 09:30
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 14:31
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:24
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3842027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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*

US3842027

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	VISIT2

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:42:03

Generated On: 10 Jun 2021 10:02:02

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)	8 OCT 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 09:56
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:42:03

Generated On: 10 Jun 2021 10:02:02

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)	8 OCT 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:48
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3842027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 OCT 2020

What was the treatment time? (00:00-23:59) 10:17 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 10:17

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

US3842027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	8 OCT 2020 09:45

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Collection date (dd MMM yyyy)			08 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:47	08 OCT 2020 09:47
Nasopharyngeal Swab 2	No		

US3842027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 10:38

PC Open Date & Time

08 OCT 2020 10:37

PC Close Date & Time

08 OCT 2020 13:07

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**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

97.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	08 OCT 2020 21:13
PC Open Date & Time	08 OCT 2020 14:02
PC Close Date & Time	09 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

09 OCT 2020 17:11

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 23:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 17:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 19:12

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**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

97.7 °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

13 OCT 2020 18:33

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 21:51

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 10:39

PC Open Date & Time

08 OCT 2020 10:37

PC Close Date & Time

08 OCT 2020 13:07

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 21:14

PC Open Date & Time

08 OCT 2020 14:02

PC Close Date & Time

09 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**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

09 OCT 2020 17:12

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**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

10 OCT 2020 23:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**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

11 OCT 2020 17:04

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**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

12 OCT 2020 19:13

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**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

13 OCT 2020 18:33

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**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

14 OCT 2020 21:52

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 10:41
PC Open Date & Time	08 OCT 2020 10:37
PC Close Date & Time	08 OCT 2020 13:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**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 ☐

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 21:15
PC Open Date & Time	08 OCT 2020 14:02
PC Close Date & Time	09 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**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)

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 17:13
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**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  
EAB) (1725)

110 of 2740

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 23:08
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

112 of 2740

EAB) (1725)

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 17:05
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

EAB) (1725)

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US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 19:14
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

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EAB) (1725)

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 18:34
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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 ☒

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 21:52
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59



US3842027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 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

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 09:36
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)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3842027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 NOV 2020
Collection time (00:00-23:59)	9:50 (24 HR)
Collection date and time (derived)	05 NOV 2020 9:50

US3842027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

<b>TIMEPOINT</b>	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 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	10 NOV 2020 14:59:53
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 12:02:46

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

TIMEPOINT	DAY 75
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	21 NOV 2020 15:18:16
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 09:15:41

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

07 DEC 2020 09:15:05

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59



US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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	12 DEC 2020 12:19:05
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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	19 DEC 2020 17:21:37
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

26 DEC 2020 12:28:00

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

04 JAN 2021 23:11:46

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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	09 JAN 2021 09:09:35
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:29:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

24 JAN 2021 06:53:28

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 17:40:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 12:28:47

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

15 FEB 2021 07:21:55

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 11:01:12

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

01 MAR 2021 14:50:54

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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	06 MAR 2021 10:36:42
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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	24 MAR 2021 10:16:13
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59



US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

27 MAR 2021 13:02:14

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 13:52:03

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 10:50:08

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 09:07:49

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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

27 APR 2021 08:29:12

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq$  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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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°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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59
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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59
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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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°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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59
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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 579

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 705

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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="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"/>



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 754

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

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

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

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

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

Fever (Temperature  $\geq$  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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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

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 ☐



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**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 ☐

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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 <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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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"/>

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2022 23:59

US3842027

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 10:02:02**

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		01 MAR 2021 14:50:33



US3842027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:54:36

Generated On: 10 Jun 2021 10:02:02

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3842027

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:54:36

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

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

Visit date (dd MMM yyyy)	08 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
------------	--------

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 APR 2021
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 09:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

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

Collection date (dd MMM yyyy)	08 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:15 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	08 APR 2021 10:15
------------------------------------	-------------------

US3842027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:32:04

Generated On: 10 Jun 2021 10:02:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842027

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

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*

**US3842027**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:02**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3842027

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>



US3842027

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3842027

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

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

Visit date (dd MMM yyyy)	13 JAN 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
------------	---------------

US3842027

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:54:35

Generated On: 10 Jun 2021 10:02:02

Date of updated informed consent (*dd MMM yyyy*) 13 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 13 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3842027

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	10:18 (24 HR)
Collection date and time (derived)	13 JAN 2021 10:18

US3842027

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 18:42:02

Generated On: 10 Jun 2021 10:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	09:55
Collection Date and Time (derived)	13 JAN 2021 09:55

US3842027

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 JAN 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

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 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)	



US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID	USA-US110-2020-MRNA-1273-P30 1000003
Adverse event	WORSENING LEFT PNEUMOTHORAX
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 DEC 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)	23 DEC 2020
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)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	23 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <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	True
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	

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

---

PARTICIPANT US3842027  
REPORTED TO STUDY RN ON 21  
DEC 2020 AT 1100 VIA TEXT  
MESSAGE THEY WERE  
ADMITTED TO AN AREA  
HOSPITAL ON SATURDAY, 19  
DEC 2020 FOR TREATMENT  
AND SURGICAL INTERVENTION  
OF A LEFT COLLAPSED LUNG  
(SEVERE, GRADE 3). COVID-19  
TEST ON ADMISSION  
NEGATIVE PER PARTICIPANT.  
PARTICIPANT WAS SCREENED,  
ENROLLED AND RECEIVED  
FIRST INJECTION ON  
MRNA1273-P301 ON 10 SEP 2020;  
RECEIPT OF SECOND  
INJECTION WAS 08 OCT 2020.  
PARTICIPANT HAS DENIED  
ANY ADVERSE EVENTS SINCE  
ENROLLMENT. MEDICAL  
HISTORY SIGNIFICANT FOR  
LEFT COLLAPSED LUNG  
(DIAGNOSED MAY 2020,  
HOSPITALIZED FOR 6 DAYS  
AND DISCHARGED RESOLVED),  
TYPE II DIABETES (DIAGNOSED  
1980), PROSTATE CANCER  
(DIAGNOSED 2008, RESOLVED  
2013), LUNG CANCER, STAGE 1  
(DIAGNOSED 2013, RESOLVED  
2013), COLON CANCER  
(DIAGNOSED 2012, RESOLVED  
2012), TRANSCATHETER  
AORTIC VALVE REPLACEMENT

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

---

(2016), AND SLEEP APNEA  
(DIAGNOSED 2010). PER  
PARTICIPANT REPORT, THEY  
WERE SCHEDULED TODAY FOR  
THE FOLLOWING  
PROCEDURES: LEFT VIDEO  
ASSISTED THORACOSCOPIC  
SURGERY (LVATS),  
BULLECTOMY AND TALC  
PLEURODESIS. PARTICIPANT  
DID NOT REPORT ANY  
ADDITIONAL INFORMATION AT  
THIS TIME AND WAS UNABLE  
TO TALK TO STUDY RN. PI HAS  
ASSESSED THIS EVENT AS NOT  
RELATED TO STUDY PRODUCT.

---

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

---

US3842027

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID	USA-US110-2020-MRNA-1273-P30 1000003
Adverse event	ACUTE HYPOXEMIA RESPIRATORY FAILURE (WORSENING)
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 DEC 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)	23 DEC 2020
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)	19 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	23 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative	USA-US110-2020-MRNA-1273-P30	
		1000003
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
<hr/>		
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US3842027

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID

Adverse event

TREMORS (HANDS) WORSENER

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)

23 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 JAN 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)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____



US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID	
Adverse event	COPD WORSENER
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)	01 DEC 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)	13 JAN 2021
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 (6)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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)	_____

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

AEID

Adverse event

SEVERE PAIN AT LEFT RIB  
CAGE, INSERTION SITE WHERE  
CHEST TUBE WAS REMOVED  
(AFTER LEFT PNEUMOTHORAX  
-RESOLVED)

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)

23 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 JAN 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 ☐

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Folder: Adverse Events

Form: Adverse Events (10)

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	No	<input type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity	False	<input type="radio"/>
Congenital anomaly or birth defect	False	<input type="radio"/>
Other medically important event	False	<input type="radio"/>
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 type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
Action taken with investigational product	None	<input checked="" type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Other action taken (check all that apply)		
None	False	<input type="radio"/>
Concomitant Medication	True	<input type="radio"/>
Concomitant Procedure	False	<input type="radio"/>
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"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

---

TRAMADOL-ACETAMINOPHEN  
37.5/325 MG PRN WAS  
PRESCRIBED AT DISCHARGE  
FOR PAIN MANAGEMENT AT  
LEFT RIB CAGE AFTER CHEST  
TUBE WAS REMOVED

---

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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US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

---

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

Yes ☒

No ☐

---

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

---

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 36

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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1980
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 DEC	2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication LEVEMIR

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 56

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 (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1980
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication TORSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication ELEVATED BLOOD PRESSURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1990
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 (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 2008	
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 (5)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication FINESTRIDE

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE CANCER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 2008	
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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1980
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 (7)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication TREMORS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication METROPROLOL TAETRATE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILATION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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) _____		
Start date completely unknown		True
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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1990
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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication POTASSIUM

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify MEQ

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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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 1995
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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)		20 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 AUG 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 (12)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication BUDESONIDE AND  
FORMOTEROL FUMARATE  
DIHYDRATE INHALATION  
AEROSOL

Prophylaxis Yes ☐  
No ☒

Indication COPD WORSENER

Dose per administration 80/4.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication HAND TREMORS WORSENING

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)	23 DEC 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 (14)

Data signed: (b) (4) 28 Apr 2021 10:32:03

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Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES II

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

BEFORE MEALS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)	23 DEC 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)	_____	
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 (15)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication LEVEMIR

Prophylaxis Yes ☐  
No ☒

Indication DIABETES II

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)	23 DEC 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 (16)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒  
No ☐

Indication DVT PREVENTION

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 (16)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)		19 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)		23 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication TRAMADOL-ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN, LEFT RIB CAGE S/P  
SURGERY, DISCHARGE TO  
HOME

Dose per administration 37.5 / 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS PRN

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) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)	23 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)		13 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	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)		23 DEC 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 (19)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication OXYGEN, SUPPLEMENTAL (VIA REBREATHING MASK)

Prophylaxis Yes ☐  
No ☒

Indication OXYGEN SATURATION 92%

Dose per administration 2

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

If dose unit is Other, specify LITER / MIN.

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 CONTINUOUS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)		19 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 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"/>

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication ALBUTEROL SULFATE (0.083 %)

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 2.5

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

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003

396 of 2740

EAB) (1725)

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

Name of Medication IPRATROPIUM BROMIDE

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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) _____		
Start date completely unknown		True
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)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Mar 2021 15:54:35

Generated On: 10 Jun 2021 10:02:02

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 DEC 2020	LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)	Adverse Event	
21 DEC 2020	BULLECTOMY	Adverse Event	
21 DEC 2020	TALC PLEURODESIS	Adverse Event	

US3842027

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

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

US3842027

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:42:01

Generated On: 10 Jun 2021 10:02:02

Date of study discontinuation/completion ( <i>dd MMM yyyy</i> )	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician decision (specify) <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol deviation (specify) <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of consent by participant (specify) <input type="checkbox"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death ( <i>dd MMM yyyy</i> )	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/DEC/2020 16:39
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/JAN/2021 15:54
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	27/JAN/2021 13:15
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



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	08/FEB/2021 09:08
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/FEB/2021 11:45
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	11/MAR/2021 07:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:41
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	17/MAR/2021 10:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	17/MAR/2021 12:20
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:02
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:27
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



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:42
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (13)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	24/MAR/2021 10:48
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (14)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	01/APR/2021 05:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (15)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	02/APR/2021 09:45
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

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (16)

Data signed: (b) (4) 28 Apr 2021 10:32:03

Generated On: 10 Jun 2021 10:02:02

SAEID	USA-US110-2020-MRNA-1273-P301000003
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	SHOBHA
Investigator's Last Name	SWAMINATHAN
Site Address: Street	185, SOUTH ORANGE AVE
Site Address: City	NEWARK
Site Address: State	
Site Address: Postal Code	07103
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	07/APR/2021 06:20
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

US3842027 (Prod: New Jersey Medical School)

**US3842027**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:02:02**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:54:09
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'US3842027'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:04:39

US3842027

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:41:53
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:38:51



US3842027

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:41:54
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:04:40

US3842027

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:41:55
User entered 'Clinic (Clinic)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:38:51

US3842027

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'SCRN'	System	10 Sep 2020 17:38:51

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:01
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:04:41

**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:03
User entered '81'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'YEARS'	System	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '81'	System	10 Sep 2020 17:40:58

**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:05
User entered 'Male (M)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42



US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:12
User entered 'I'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:14
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:15
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:18
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:20
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:22
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:26
User entered empty.	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42



**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:27
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

**US3842027**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:02**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:49:29
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:39:42

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:12
User entered '10 Sep 2020'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Sep 2020'	System	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2020'	System	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:14
User entered 'Amendment 3 (3)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:15
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58

**US3842027**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:17
User entered empty.	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58



**US3842027**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:02**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:18
User entered empty.	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:22
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:40:58

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:50:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:04:40

US3842027

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'I'	System	10 Sep 2020 17:41:02

US3842027

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:54:09
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:41:02

US3842027

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:02:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:14:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:17:42

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Pneumothorax - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Feb 2021 08:49:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 08:49:43
Data point term sent to Coder	System	05 Feb 2021 23:23:38
Coding entries removed.	Christie Lyn Costanza	05 Feb 2021 23:23:05
User entered 'left pneumothorax' reason for change: Data Entry Error	(b) (4) Christie Lyn Costanza	05 Feb 2021 23:23:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Collapse of lung - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Sep 2020 16:30:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:30:53
Data point term sent to Coder	System	18 Sep 2020 16:30:16
User entered 'Collapsed Lung'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User closed query 'please review source log as start date is stated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:42:22
Query 'please review source log as start date is stated' answered with 'confirmed with source and updated' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:11:18
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:09:51
User entered '03 May 2020' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:09:51
User opened query 'please review source log as start date is stated' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:02:27
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:25:42
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '3 May 2020' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:32:15
User entered empty.	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:30:12



US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). Signature has been broken.	System	20 Apr 2021 16:10:39
User entered '0' reason for change: Per Query Resolution	Malithi Desilva (b) (4) Malithi Desilva (b) (4)	20 Apr 2021 16:10:39
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). User signature succeeded.	System	20 Apr 2021 16:09:51
Signature has been broken.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered '1' reason for change: New Information	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:25:42
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered '0' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:32:15
User entered '1'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	21 Apr 2021 20:43:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	21 Apr 2021 20:43:41
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	21 Apr 2021 20:43:41
User entered '09 May 2020' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	21 Apr 2021 20:43:41
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 16:30:12
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'May 2020'	System	20 Apr 2021 16:09:51
User entered empty.	System	16 Mar 2021 17:25:42
User entered 'May 2020'	System	18 Sep 2020 16:32:15
User entered empty.	System	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2020'	System	20 Apr 2021 16:09:51
User entered empty.	System	16 Mar 2021 17:25:42
User entered '2020'	System	18 Sep 2020 16:32:15
User entered empty.	System	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'May 2020'	System	21 Apr 2021 20:43:41
User entered empty.	System	18 Sep 2020 16:30:12

US3842027

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2020'	System	21 Apr 2021 20:43:41
User entered empty.	System	18 Sep 2020 16:30:12



US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
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 II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:00:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:00:33
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
Data point term sent to Coder	System	23 Mar 2021 14:37:28
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:36:59
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:36:59
User entered 'TYPE II DIABETES (insulin dependent)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:36:59
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
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 II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:33:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:33:00
Data point term sent to Coder	System	18 Sep 2020 16:32:20
User entered 'Type II Diabetes'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:31:30

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 1980' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	18 Sep 2020 16:32:48
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:31:30
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:32:48
User entered '1'	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:31:30
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4)	18 Sep 2020 16:31:34
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	18 Sep 2020 16:31:30
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:31:30

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:31:30

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:31:34
User entered '1'	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:31:30
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 1980'	System	18 Sep 2020 16:32:48
User entered empty.	System	18 Sep 2020 16:31:30

**US3842027**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '1980'	System	18 Sep 2020 16:32:48
User entered empty.	System	18 Sep 2020 16:31:30



US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	18 Sep 2020 16:31:30

US3842027

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	18 Sep 2020 16:31:30

US3842027

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:03
Data point term sent to Coder	System	18 Sep 2020 16:33:25
User entered 'Prostate Cancer'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:19

US3842027

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 19:02:23
User entered 'UN UNK 2008' reason for change: Per Malithi Desilva	(b) (4)	09 Dec 2020 14:45:33
Query Resolution	(b) (4)	
User entered 'un UNK 2013'	Malithi Desilva (b) (4)	18 Sep 2020 16:33:19
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:19

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:19

US3842027

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	20 Apr 2021 16:19:42
User entered 'UN UNK 2013' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	20 Apr 2021 16:19:42
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:33:19
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	20 Apr 2021 16:19:42
User entered '0' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	20 Apr 2021 16:19:42
User signature succeeded.	(b) (4) Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '1'	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 16:33:19



**US3842027**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2008'	System	09 Dec 2020 14:45:33
User entered 'Jan 2013'	System	18 Sep 2020 16:33:19

**US3842027**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2008'	System	09 Dec 2020 14:45:33
User entered '2013'	System	18 Sep 2020 16:33:19

US3842027

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2013'	System	20 Apr 2021 16:19:42
User entered empty.	System	18 Sep 2020 16:33:19

US3842027

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2013'	System	20 Apr 2021 16:19:42
User entered empty.	System	18 Sep 2020 16:33:19

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Lung neoplasm malignant, LLT: Lung cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:49
Data point term sent to Coder	System	18 Sep 2020 16:34:27
User entered 'Lung Cancer'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 2013'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 20:25:48
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	18 Sep 2020 16:33:38
User entered 'No (N)'	Malithi Desilva (b) (4)	18 Sep 2020 16:33:38



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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	20 Apr 2021 16:22:15
User entered 'UN UNK 2013' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	20 Apr 2021 16:22:15
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:33:38
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	(b) (4), (b) (6)	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	20 Apr 2021 16:22:15
User entered '0' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	20 Apr 2021 16:22:15
User signature succeeded.	(b) (4) Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '1' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 20:25:48
User entered '0'	(b) (4) Malithi Desilva (b) (4)	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2013'	System	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2013'	System	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2013'	System	20 Apr 2021 16:22:15
User entered empty.	System	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2013'	System	20 Apr 2021 16:22:15
User entered empty.	System	18 Sep 2020 16:33:38

US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer, LLT: Colon cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:34:49
Data point term sent to Coder	System	18 Sep 2020 16:34:27
User entered 'Colon Cancer'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:57

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 2012'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:57



US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:57

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:57

US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4)	20 Apr 2021 16:12:47
User entered 'un UNK 2012' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	20 Apr 2021 16:12:47
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:33:57
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User closed query 'please review response as source states the year 2012. review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:45:18
Query 'please review response as source states the year 2012. review and update accordingly.' answered with 'confirmed with source and updated' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:13:07
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:12:47
User entered '0' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:12:47
User opened query 'please review response as source states the year 2012. review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:05:10
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered '1'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:33:57

US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2012'	System	18 Sep 2020 16:33:57

**US3842027**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2012'	System	18 Sep 2020 16:33:57

US3842027

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2012'	System	20 Apr 2021 16:12:47
User entered empty.	System	18 Sep 2020 16:33:57

**US3842027**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2012'	System	20 Apr 2021 16:12:47
User entered empty.	System	18 Sep 2020 16:33:57



US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Heart valve replacement, LLT: Heart valve replacement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 18:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:50:41
Data point term sent to Coder	System	18 Sep 2020 16:34:27
User entered 'Heart Valve TAVR REplacement'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 2016'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

**US3842027**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:15:02
User entered 'UN UNK 2016' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:15:02
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User closed query 'please review response as source states stop date of 2016. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:46:15
Query 'please review response as source states stop date of 2016. Please review and update accordingly.' answered with 'confirmed with source and updated' (Site from CRA).	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:15:27
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:15:02
User entered '0' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	20 Apr 2021 16:15:02
User opened query 'please review response as source states stop date of 2016. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:06:08
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered '1'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2016'	System	18 Sep 2020 16:34:22

**US3842027**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2016'	System	18 Sep 2020 16:34:22



US3842027

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2016'	System	20 Apr 2021 16:15:02
User entered empty.	System	18 Sep 2020 16:34:22

**US3842027**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2016'	System	20 Apr 2021 16:15:02
User entered empty.	System	18 Sep 2020 16:34:22

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Sep 2020 09:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:09:53
Data point term sent to Coder	System	18 Sep 2020 16:35:30
User entered 'Sleep Apnea'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 2010'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:34:57



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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2010'	System	18 Sep 2020 16:34:57

**US3842027**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2010'	System	18 Sep 2020 16:34:57

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	18 Sep 2020 16:34:57

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 16:37:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:37:16
Data point term sent to Coder	System	18 Sep 2020 16:35:32
User entered 'Cataract Surgery'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:35:22

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'un UNK 2019'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 16:35:22



US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'UN UNK 2019' reason for change:	(b) (4)	
Data Entry Error	Malithi Desilva (b) (4)	08 Oct 2020 20:21:17
User entered empty.	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:35:22
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	08 Oct 2020 20:21:17
User entered '1'	(b) (4)	
	Malithi Desilva (b) (4)	18 Sep 2020 16:35:22
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2019'	System	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2019'	System	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2019'	System	08 Oct 2020 20:21:17
User entered empty.	System	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2019'	System	08 Oct 2020 20:21:17
User entered empty.	System	18 Sep 2020 16:35:22

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 08:31:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:31:56
Data point term sent to Coder	System	10 Mar 2021 22:52:47
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:52:16
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:52:16
User entered 'TREMORS, hands' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:52:16
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 21:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 21:40:58
Data point term sent to Coder	System	11 Dec 2020 21:39:49
User entered 'Tremors'	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'UN UNK 2010'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45



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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 2010'	System	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2010'	System	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:39:45

US3842027

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:39:45



US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 21:47:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 21:47:29
Data point term sent to Coder	System	11 Dec 2020 21:45:59
User entered 'elevated blood pressure'	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'UN UNK 1990'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'Jan 1990'	System	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '1990'	System	11 Dec 2020 21:45:44



**US3842027**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:45:44

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Dec 2020 21:47:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 21:47:49
Data point term sent to Coder	System	11 Dec 2020 21:47:00
User entered 'atrial fibrillation'	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'I'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:57



US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	11 Dec 2020 21:46:57

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 21:03:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 22:17:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 22:17:57
Query 'Per MM, please expand the abbreviation' answered with 'updated per query' (Site from DM).	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:17:52
Data point term sent to Coder	System	19 Feb 2021 22:17:39
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:17:38
User entered 'COPD (Chronic obstructive pulmonary disease)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:17:38
User opened query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:09:07
Query 'Per MM, please expand the abbreviation' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:08:56
User opened query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:08:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:28:08
Data point term sent to Coder	System	21 Jan 2021 22:26:35
User entered 'COPD'	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 22:26:03

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Jan 2021 22:29:08
User entered 'un May 2020' reason for change: Data Entry Error	System	21 Jan 2021 22:29:08
User entered 'un May 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	21 Jan 2021 22:29:08
User entered 'un May 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Jan 2021 22:26:03
User entered ' May 2020' (non-conformant).	Mario Portilla (b) (4)	21 Jan 2021 22:26:03
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	21 Jan 2021 22:26:03
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	21 Jan 2021 22:26:03
	(b) (4)	



US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	21 Jan 2021 22:26:03
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	21 Jan 2021 22:26:03
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'May 2020'	System	21 Jan 2021 22:29:08
User entered empty.	System	21 Jan 2021 22:26:03

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '2020'	System	21 Jan 2021 22:29:08
User entered empty.	System	21 Jan 2021 22:26:03

US3842027

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	21 Jan 2021 22:26:03

**US3842027**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	21 Jan 2021 22:26:03

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
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.	(b) (4) Coder Import (b) (4)	12 Mar 2021 11:32:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:32:44
Data point term sent to Coder	System	10 Mar 2021 22:25:57
User entered "benign prostatic hyperplasia,"	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:25:42

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	10 Mar 2021 22:25:42
	(b) (4)	



US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:25:42

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:25:42

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	10 Mar 2021 22:25:42
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	10 Mar 2021 22:25:42
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	10 Mar 2021 22:25:42

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	10 Mar 2021 22:25:42

US3842027

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	10 Mar 2021 22:25:42

**US3842027**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	10 Mar 2021 22:25:42



US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:49
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:04:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:04:52
Data point term sent to Coder	System	16 Mar 2021 17:03:53
User entered 'ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX)'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty; reason for change Data Entry Error	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 17:27:05
User entered '15 May 2020'	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '1' reason for change: New Information	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 17:27:05
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	16 Mar 2021 17:03:05
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:27:05
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty; reason for change New Information	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:27:05
User entered '16 May 2020'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 17:03:05
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	16 Mar 2021 17:27:05
User entered 'May 2020'	System	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	16 Mar 2021 17:27:05
User entered '2020'	System	16 Mar 2021 17:03:05



**US3842027**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	16 Mar 2021 17:27:05
User entered 'May 2020'	System	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	16 Mar 2021 17:27:05
User entered '2020'	System	16 Mar 2021 17:03:05

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:41:05
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Per query, additional information has been added' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:31:49
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 16:40:04
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:42:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:42:36
Data point term sent to Coder	System	23 Mar 2021 14:41:33
User entered 'asthma'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:40:50



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Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:40:50

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 14:42:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:42:38
Data point term sent to Coder	System	23 Mar 2021 14:41:33
User entered 'pulmonary nodules'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:41:22

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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'I'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:42:32
User entered 'Yes (Y)'	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:41:22
	(b) (4)	



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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:42:32
User entered '0'	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:41:22
	(b) (4)	

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Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:41:22

**US3842027**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:41:22

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:36:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:36:32
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
Data point term sent to Coder	System	23 Mar 2021 14:42:34
User entered 'distant lung lymphadenopathy benign'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:42:01



US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	23 Mar 2021 14:42:38
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	23 Mar 2021 14:42:01
User entered 'No (N)'	Malithi Desilva (b) (4)	23 Mar 2021 14:42:01

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Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:42:38
User entered '0'	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 14:42:01
	(b) (4)	

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:42:01

US3842027

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:42:01



US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Ileostomy, LLT: Ileostomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	23 Mar 2021 15:00:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 15:00:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Ileostomy, LLT: Ileostomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:45:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 14:45:38
Data point term sent to Coder	System	23 Mar 2021 14:44:38
User entered 'ileostomy'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

**US3842027**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 10:02:02**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:43:43



US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:43:43

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:31:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:31:27
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
Data point term sent to Coder	System	23 Mar 2021 14:45:39
User entered 'chronic bilateral lower extremity edema (secondary to venous insufficiency)'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:44:53



US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:44:53

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
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.	(b) (4) Coder Import (b) (4)	23 Mar 2021 14:46:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 14:46:37
Data point term sent to Coder	System	23 Mar 2021 14:45:39
User entered 'benign prostate hyperplasia'	Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27



US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:50:01
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	23 Mar 2021 14:45:27

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:32:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 17:32:22
Data point term sent to Coder	System	06 Apr 2021 17:31:25
User entered 'Constipation'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45

**US3842027**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45



US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User entered 'I'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:50:01
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	06 Apr 2021 17:30:45

US3842027

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	06 Apr 2021 17:30:45



US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:55:05
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:55:22
User entered '10 Sep 2020'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:37:16
DataPoint Un-verified.	Malithi Desilva (b) (4)	21 Apr 2021 20:30:18
Signature has been broken.	(b) (4) Malithi Desilva (b) (4)	21 Apr 2021 20:30:18
User entered '10:30' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	21 Apr 2021 20:30:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:55:20
User entered '10:32'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 10:30'	System	21 Apr 2021 20:30:18
User entered '10 Sep 2020 10:32'	System	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:55:26
User entered '174.2' cm	Christie Lyn Costanza	15 Sep 2020 17:29:22
DataPoint set to visible.	(b) (4) System	10 Sep 2020 17:41:02

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:55:29
User entered '110' kg	Christie Lyn Costanza	15 Sep 2020 17:29:22
DataPoint set to visible.	(b) (4) System	10 Sep 2020 17:41:02

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '36.24903'	System	15 Sep 2020 17:29:22
DataPoint set to visible.	System	10 Sep 2020 17:41:02

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'kg/m2'	System	15 Sep 2020 17:29:22
DataPoint set to visible.	System	10 Sep 2020 17:41:02



US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User closed query 'please review source for all vitals as vitals have been captured per source. please update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 20:37:12
Query 'please review source for all vitals as vitals have been captured per source. please update accordingly' answered with 'per CCG V5 pg. 24-25 scenario 2, participant was screened, enrolled, randomized, and dosed the same day. CCG instructs this field and fields below recorded as 'ND'. Please confirm if otherwise. ' (Site from CRA).	Malithi Desilva (b) (4)	20 Apr 2021 16:08:20
User opened query 'please review source for all vitals as vitals have been captured per source. please update accordingly' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:57:52
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 22:55:37
User entered '98.9' F	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User entered empty; reason for change Data Entry Error	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 22:55:39
User entered 'Oral (Oral)'	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	15 Sep 2020 17:29:22
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:24:51
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 22:55:47
User entered '79'	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'bpm'	System	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:24:51
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 22:55:49
User entered '24'	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'breaths/min'	System	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User closed query 'Please confirm as source states 149/69.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 14:54:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
Query 'Please confirm as source states 149/69.' answered with 'Repeat BP is 148/70. initial BP was 149/69. ' (Site from CRA).	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User opened query 'Please confirm as source states 149/69.' (Site from CRA).	(b) (4)	
User entered '148'	Malithi Desilva (b) (4)	18 Sep 2020 16:41:34
	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 22:56:15
	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	



US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:37:16
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	Malithi Desilva (b) (4)	19 Oct 2020 17:24:51
User entered '70'	(b) (4)	
	Christie Lyn Costanza	15 Sep 2020 17:29:22
	(b) (4)	

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:29:22

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54

US3842027

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54

US3842027

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:31
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:45:26

US3842027

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:34
User entered '10 Sep 2020'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:45:26

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:40
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40



US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:42
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:45
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:51
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:53
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:55
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:56:57
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:01
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:03
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:04
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:07
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:20
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:22
User entered empty.	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'I'	(b) (4)	10 Sep 2020 17:46:40
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:37
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

**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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:36
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:35
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

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)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:34
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:42
User entered '0'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '0'	(b) (4)	10 Sep 2020 17:46:40
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:57:43
User entered empty.	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:40

US3842027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:25:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:42:22

US3842027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:25:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 Sep 2020'	(b) (4)	10 Sep 2020 17:42:22
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:25:53
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Clinic (Clinic)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:42:22

US3842027

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'VISIT1'	System	10 Sep 2020 17:42:22



US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:33

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '189399'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:33

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:40:33

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4) Christie Lyn Costanza	10 Sep 2020 17:43:57
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:43:57

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:43:57

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:43:57

US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:43:57



US3842027

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:02

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:28:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4)	19 Oct 2020 17:23:58
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:57:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:56:59

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:27:10
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:15:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:24:30
User entered '174.2' cm	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:15:57
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	19 Oct 2020 17:15:50
User entered '110' kg	Christie Lyn Costanza	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:27:10
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:15:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:24:30
User entered '174.2' cm	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:15:57
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	19 Oct 2020 17:15:50
User entered '110' kg	Christie Lyn Costanza	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User accepted default value 'Pre-Dose (PREDOSE)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 Sep 2020'	(b) (4) Christie Lyn Costanza	15 Sep 2020 17:28:17
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:31:23
Signature has been broken.	Malithi Desilva (b) (4)	21 Apr 2021 20:30:28
User entered '10:30' reason for change: Data Entry Error	(b) (4) Malithi Desilva (b) (4)	21 Apr 2021 20:30:28
User signature succeeded.	(b) (4) Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10:32'	(b) (4) Christie Lyn Costanza	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 10:30'	System	21 Apr 2021 20:30:28
User entered '10 Sep 2020 10:32'	System	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '98.9' F	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Oral (Oral)'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '79'	(b) (4) Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'bpm'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '24'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'breaths/min'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '148'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '70'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:27:10
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:16:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:15:50
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 10:24:30
User entered '174.2' cm	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:02

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:15:57
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4)	19 Oct 2020 17:15:50
User entered '110' kg	Christie Lyn Costanza	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User accepted default value 'Post-Dose (POSTDOSE)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 Sep 2020'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User closed query 'Per CDM: The treatment time on the Exposure CRF is 13:09 and the Vital Signs Post Dose Time of Assessment is 13:09 which are same. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:30:05
Query 'Per CDM: The treatment time on the Exposure CRF is 13:09 and the Vital Signs Post Dose Time of Assessment is 13:09 which are same. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' answered with 'data entry error. confirmed with EPIC and corrected ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:23:41
User entered '13:45' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:23:21
User entered '11:36' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	19 Oct 2020 17:22:49
User opened query 'Per CDM: The treatment time on the Exposure CRF is 13:09 and the Vital Signs Post Dose Time of Assessment is 13:09 which are same. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 08:47:22
User entered '13:09'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 13:45'	System	19 Oct 2020 17:23:21
User entered '10 Sep 2020 11:36'	System	19 Oct 2020 17:22:49
User entered '10 Sep 2020 13:09'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '99.5' F	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Oral (Oral)'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '93'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'bpm'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '16'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'breaths/min'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '151'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:28:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:23
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '75'	(b) (4)	15 Sep 2020 17:28:17
	Christie Lyn Costanza	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'mmHg'	System	15 Sep 2020 17:28:17

US3842027

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	10 Sep 2020 17:46:55
	Christie Lyn Costanza	
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:31:49
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 Sep 2020'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:46:55

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:44:34

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	10 Sep 2020 17:44:34
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	10 Sep 2020 17:44:34
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10 Sep 2020'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13:09'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 13:09'	System	10 Sep 2020 17:44:34



US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christie Lyn Costanza (b) (4)	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:33:57
User entered 'ONCE'	System	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 17:44:34

US3842027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:11
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:35

US3842027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:13
User entered '10 Sep 2020'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:35

US3842027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:15
User entered '12:00'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:35

US3842027

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 12:00'	System	15 Sep 2020 17:14:35

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:26
User entered '10 Sep 2020'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:58



US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:58

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:31
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:58

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:31
User entered '12:10'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:58

**US3842027**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '10 Sep 2020 12:10'	System	15 Sep 2020 17:14:58

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Christie Lyn Costanza (b) (4)	15 Sep 2020 17:14:58

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:30:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4)	15 Sep 2020 17:14:58
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:30:34
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	15 Sep 2020 17:14:58
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered empty.	System	15 Sep 2020 17:14:58



US3842027

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 22:58:42
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	10 Sep 2020 17:42:27

US3842027

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered '1'	System	10 Sep 2020 17:42:27

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:55:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '07847f05-5477-40d7-9a71-7ed4cac068fb'	System	10 Sep 2020 17:57:59
User entered 'Yes (Y)'	System	10 Sep 2020 17:57:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:55:30', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '07847f05-5477-40d7-9a71-7ed4cac068fb' User entered '99.5'	System	10 Sep 2020 17:57:59
	System	10 Sep 2020 17:57:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:52', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '07847f05-5477-40d7-9a71-7ed4cac068fb'	System	10 Sep 2020 17:57:59
User entered 'No (N)'	System	10 Sep 2020 17:57:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:56', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '07847f05-5477-40d7-9a71-7ed4cac068fb'	System	10 Sep 2020 17:57:59
User entered '10 Sep 2020 13:57'	System	10 Sep 2020 17:57:59

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 2'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 3'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 4'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:15', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '34bfe7b7-ebdb-4aaf-864e-7fe292828794'	System	14 Sep 2020 13:30:45
User entered 'Yes (Y)'	System	14 Sep 2020 13:30:45

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:26', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '34bfe7b7-ebdb-4aaf-864e-7fe292828794' User entered '97.4'	System	14 Sep 2020 13:30:45
	System	14 Sep 2020 13:30:45

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '34bfe7b7-ebdb-4aaf-864e-7fe292828794'	System	14 Sep 2020 13:30:45
User entered 'No (N)'	System	14 Sep 2020 13:30:45



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:39', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '34bfe7b7-ebdb-4aaf-864e-7fe292828794'	System	14 Sep 2020 13:30:45
User entered '14 Sep 2020 09:30'	System	14 Sep 2020 13:30:45

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 5'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 6'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:28:11', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7168f5d-dc2d-4f5b-b05f-df97e26ba5e4'	System	15 Sep 2020 18:29:50
User entered 'Yes (Y)'	System	15 Sep 2020 18:29:50

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:29:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7168f5d-dc2d-4f5b-b05f-df97e26ba5e4' User entered '97.7'	System	15 Sep 2020 18:29:50
	System	15 Sep 2020 18:29:50

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:29:38', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7168f5d-dc2d-4f5b-b05f-df97e26ba5e4'	System	15 Sep 2020 18:29:50
User entered 'No (N)'	System	15 Sep 2020 18:29:50



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:29:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7168f5d-dc2d-4f5b-b05f-df97e26ba5e4'	System	15 Sep 2020 18:29:50
User entered '15 Sep 2020 14:29'	System	15 Sep 2020 18:29:50

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 7'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ae7e5867-9070-4f6d-bcce-968f5425abd6'	System	16 Sep 2020 19:23:41
User entered 'Yes (Y)'	System	16 Sep 2020 19:23:41

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:22', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ae7e5867-9070-4f6d-bcce-968f5425abd6'	System	16 Sep 2020 19:23:41
User entered '97.7'	System	16 Sep 2020 19:23:41

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ae7e5867-9070-4f6d-bcce-968f5425abd6'	System	16 Sep 2020 19:23:41
User entered 'No (N)'	System	16 Sep 2020 19:23:41

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ae7e5867-9070-4f6d-bcce-968f5425abd6'	System	16 Sep 2020 19:23:41
User entered '16 Sep 2020 15:23'	System	16 Sep 2020 19:23:41



US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:56:30', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f3505719-36a7-430d-a083-3e28af7ede55'	System	10 Sep 2020 17:57:10
User entered 'None (1)'	System	10 Sep 2020 17:57:10

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:56:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f3505719-36a7-430d-a083-3e28af7ede55'	System	10 Sep 2020 17:57:10
User entered 'No (N)'	System	10 Sep 2020 17:57:10

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:56:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f3505719-36a7-430d-a083-3e28af7ede55'	System	10 Sep 2020 17:57:10
User entered 'No (N)'	System	10 Sep 2020 17:57:10

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:56:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f3505719-36a7-430d-a083-3e28af7ede55'	System	10 Sep 2020 17:57:10
User entered 'None (1)'	System	10 Sep 2020 17:57:10

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f3505719-36a7-430d-a083-3e28af7ede55'	System	10 Sep 2020 17:57:10
User entered '10 Sep 2020 13:57'	System	10 Sep 2020 17:57:10



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 2'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 3'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 4'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ced1930c-aa30-4fc1-870b-cd2ce5cf9ac5'	System	14 Sep 2020 13:31:24
User entered 'None (1)'	System	14 Sep 2020 13:31:24

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ced1930c-aa30-4fc1-870b-cd2ce5cf9ac5'	System	14 Sep 2020 13:31:24
User entered 'No (N)'	System	14 Sep 2020 13:31:24

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:31:02', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ced1930c-aa30-4fc1-870b-cd2ce5cf9ac5'	System	14 Sep 2020 13:31:24
User entered 'No (N)'	System	14 Sep 2020 13:31:24

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:31:11', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ced1930c-aa30-4fc1-870b-cd2ce5cf9ac5'	System	14 Sep 2020 13:31:24
User entered 'None (1)'	System	14 Sep 2020 13:31:24

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:31:20', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ced1930c-aa30-4fc1-870b-cd2ce5cf9ac5'	System	14 Sep 2020 13:31:24
User entered '14 Sep 2020 09:31'	System	14 Sep 2020 13:31:24

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 5'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 6'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:29:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f5a54d5c-3fcb-423a-9a08-e7294a26d784'	System	15 Sep 2020 18:30:50
User entered 'None (1)'	System	15 Sep 2020 18:30:50

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:02', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f5a54d5c-3fcb-423a-9a08-e7294a26d784'	System	15 Sep 2020 18:30:50
User entered 'No (N)'	System	15 Sep 2020 18:30:50

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f5a54d5c-3fcb-423a-9a08-e7294a26d784'	System	15 Sep 2020 18:30:50
User entered 'No (N)'	System	15 Sep 2020 18:30:50

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f5a54d5c-3fcb-423a-9a08-e7294a26d784'	System	15 Sep 2020 18:30:50
User entered 'None (1)'	System	15 Sep 2020 18:30:50

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:25', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f5a54d5c-3fcb-423a-9a08-e7294a26d784'	System	15 Sep 2020 18:30:50
User entered '15 Sep 2020 14:30'	System	15 Sep 2020 18:30:50



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 7'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dbf04e07-5c15-4b8d-8a4f-220a6e7c2329'	System	16 Sep 2020 19:24:14
User entered 'None (1)'	System	16 Sep 2020 19:24:14

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:52', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dbf04e07-5c15-4b8d-8a4f-220a6e7c2329'	System	16 Sep 2020 19:24:14
User entered 'No (N)'	System	16 Sep 2020 19:24:14

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:23:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dbf04e07-5c15-4b8d-8a4f-220a6e7c2329'	System	16 Sep 2020 19:24:14
User entered 'No (N)'	System	16 Sep 2020 19:24:14

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dbf04e07-5c15-4b8d-8a4f-220a6e7c2329'	System	16 Sep 2020 19:24:14
User entered 'None (1)'	System	16 Sep 2020 19:24:14

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:11', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dbf04e07-5c15-4b8d-8a4f-220a6e7c2329'	System	16 Sep 2020 19:24:14
User entered '16 Sep 2020 15:24'	System	16 Sep 2020 19:24:14



US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:16', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:20', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:24', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:27', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:30', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'None (0)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered 'No (N)'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-10T13:57:40', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2bf2d496-9655-4e9b-8cf2-3ad6ef780e5c'	System	10 Sep 2020 17:57:43
User entered '10 Sep 2020 13:57'	System	10 Sep 2020 17:57:43

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 13:29'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 15:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 2'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 3'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 4'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:15', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:19', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:39', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'None (0)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:29:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered 'No (N)'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-14T09:30:04', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b0def941-0541-4778-8fce-92779834d18a'	System	14 Sep 2020 13:30:08
User entered '14 Sep 2020 09:30'	System	14 Sep 2020 13:30:08

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 5'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 6'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:39', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:44', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:30:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:31:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'None (0)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:31:07', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered 'No (N)'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-15T14:31:18', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '38f4f0c1-0b4c-4408-b3ed-187254667d9a'	System	15 Sep 2020 18:31:21
User entered '15 Sep 2020 14:31'	System	15 Sep 2020 18:31:21

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 7'	System	10 Sep 2020 17:44:34



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:18', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e' User entered 'None (0)'	System	16 Sep 2020 19:25:02
	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:22', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e' User entered 'None (0)'	System	16 Sep 2020 19:25:02
	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:26', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e' User entered 'None (0)'	System	16 Sep 2020 19:25:02
	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:30', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e' User entered 'None (0)'	System	16 Sep 2020 19:25:02
	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e' User entered 'None (0)'	System	16 Sep 2020 19:25:02
	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e'	System	16 Sep 2020 19:25:02
User entered 'None (0)'	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e'	System	16 Sep 2020 19:25:02
User entered 'No (N)'	System	16 Sep 2020 19:25:02

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-09-16T15:24:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '4abd7425-1962-408e-a597-c755d4a1598e'	System	16 Sep 2020 19:25:02
User entered '16 Sep 2020 15:24'	System	16 Sep 2020 19:25:02



US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:44:34

US3842027

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:18:50
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	18 Sep 2020 23:08:22

US3842027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:18:50
User entered '18 Sep 2020'	Christie Lyn Costanza (b) (4)	18 Sep 2020 23:08:22

US3842027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:18:50
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	18 Sep 2020 23:08:22

US3842027

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:18:50
User entered empty.	Christie Lyn Costanza (b) (4)	18 Sep 2020 23:08:22

US3842027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:38
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	18 Sep 2020 23:08:27

US3842027

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'I'	System	18 Sep 2020 23:08:27



US3842027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:34:45
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	28 Sep 2020 23:39:37

US3842027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:34:45
User entered '25 Sep 2020'	Christie Lyn Costanza (b) (4)	28 Sep 2020 23:39:37

US3842027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:34:45
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	28 Sep 2020 23:39:37

US3842027

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:34:45
User entered empty.	Christie Lyn Costanza (b) (4)	28 Sep 2020 23:39:37

US3842027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:34:51
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	28 Sep 2020 23:39:42

US3842027

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'I'	System	28 Sep 2020 23:39:42

**US3842027**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:37:39
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	06 Oct 2020 00:50:16

US3842027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 14:55:15
User closed query 'please verify the date of contact as the source emr encounter states 05Oct2020. Please review, verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 14:55:13
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Query 'please verify the date of contact as the source emr encounter states 05Oct2020. Please review, verify and update accordingly.' answered with 'safety call made 03OCT2020, note was written by study RN 05OCT2020' (Site from CRA).	(b) (4)	
	Malithi Desilva	(b) (4) 06 Nov 2020 23:31:29
	(b) (4)	
User opened query 'please verify the date of contact as the source emr encounter states 05Oct2020. Please review, verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:37:01
User entered '03 Oct 2020'	Christie Lyn Costanza	06 Oct 2020 00:50:16
	(b) (4)	



US3842027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:37:41
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	06 Oct 2020 00:50:16

US3842027

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:37:44
User entered empty.	Christie Lyn Costanza (b) (4)	06 Oct 2020 00:50:16

US3842027

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:37:54
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	06 Oct 2020 00:50:08

US3842027

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:35:54
User entered 'I'	System	06 Oct 2020 00:50:08

US3842027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:49:13
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:21:17

**US3842027**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:49:13
User entered '08 Oct 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:21:17

US3842027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:49:13
User entered 'Clinic (Clinic)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:21:17

US3842027

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'VISIT2'	System	08 Oct 2020 14:21:17



US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User accepted default value 'Pre-Dose (PREDOSE)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '8 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:18:22
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Un-verified.	(b) (4)	
	Malithi Desilva (b) (4)	06 Nov 2020 23:22:32
User entered '09:56' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 23:22:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '08:34'	Malithi Desilva (b) (4)	08 Oct 2020 19:04:37
	(b) (4)	

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '8 Oct 2020 09:56'	System	06 Nov 2020 23:22:32
User entered '8 Oct 2020 08:34'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:18:26
User closed query 'please review temperature entry as source states temperature of 98.2. please review source, verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:17:48
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Query 'please review temperature entry as source states temperature of 98.2. please review source, verify and update accordingly.' answered with 'confirmed with source document and EPIC, corrected' (Site from CRA).	(b) (4)	
	Malithi Desilva (b) (4)	06 Nov 2020 23:22:55
	(b) (4)	
User entered '98.2' F reason for change: Data Entry Error	Malithi Desilva (b) (4)	06 Nov 2020 23:22:32
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 14:59:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:59:19
	(b) (4), (b) (6)	
User opened query 'please review temperature entry as source states temperature of 98.2. please review source, verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:51:27
	(b) (4), (b) (6)	
User entered '98.4' F	Malithi Desilva (b) (4)	08 Oct 2020 19:04:37
	(b) (4)	

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered 'Oral (Oral)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered empty.	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37



US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:18:26
User closed query 'please review pulse entry as it is inconsistent with source response of "84". Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:18:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Query 'please review pulse entry as it is inconsistent with source response of "84". Please review and update accordingly. ' answered with 'confirmed with source document and EPIC, corrected' (Site from CRA).	(b) (4) Malithi Desilva (b) (4)	06 Nov 2020 23:22:59
User entered '84' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 23:22:32
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 14:59:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:59:19
User opened query 'please review pulse entry as it is inconsistent with source response of "84". Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:57:41
User entered '83'	Malithi Desilva (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'bpm'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '20'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'breaths/min'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '130'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '65'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	08 Oct 2020 19:04:37



US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User accepted default value 'Post-Dose (POSTDOSE)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '8 Oct 2020'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '10:48'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '8 Oct 2020 10:48'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '98.6' F	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered 'Oral (Oral)'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered empty.	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37



US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '83'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'bpm'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 19:10:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 19:10:38
User entered '20' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:10:38
Comment added 'respiration was missed'.	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:05:05
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 19:04:37
User entered empty.	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'breaths/min'	System	08 Oct 2020 19:10:38
User entered empty.	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '138'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:59:19
User entered '65'	Malithi Desilva (b) (4) (b) (4)	08 Oct 2020 19:04:37

US3842027

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	08 Oct 2020 19:04:37



US3842027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:00:27
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:21:47

US3842027

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:00:27
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:21:47

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

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 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered '08 Oct 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered '10:17'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10



US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '08 Oct 2020 10:17'	System	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered 'Left Arm (LEFT ARM)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:01:44
User entered 'ONCE'	System	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 14:22:10

US3842027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:19
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:30

US3842027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:19
User entered '8 Oct 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:30

US3842027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:19
User entered '09:45'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:30

US3842027

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '8 Oct 2020 09:45'	System	08 Oct 2020 14:22:30



US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:36
User entered '08 Oct 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

**US3842027**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:36
User entered '09:47'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '08 Oct 2020 09:47'	System	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44

**US3842027**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:44



US3842027

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:02:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered empty.	System	08 Oct 2020 14:22:44

US3842027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:02:45
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:22:48

US3842027

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'I'	System	08 Oct 2020 14:22:48

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:38:26', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7e3ce946-3880-46a2-bdab-fbea32dacd84'	System	08 Oct 2020 14:38:57
User entered 'Yes (Y)'	System	08 Oct 2020 14:38:57

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:38:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7e3ce946-3880-46a2-bdab-fbea32dacd84'	System	08 Oct 2020 14:38:57
User entered '97.2'	System	08 Oct 2020 14:38:57

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:38:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7e3ce946-3880-46a2-bdab-fbea32dacd84'	System	08 Oct 2020 14:38:57
User entered 'No (N)'	System	08 Oct 2020 14:38:57

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:38:55', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7e3ce946-3880-46a2-bdab-fbea32dacd84'	System	08 Oct 2020 14:38:57
User entered '08 Oct 2020 10:38'	System	08 Oct 2020 14:38:57



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 10:37'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 13:07'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:12:51', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b9fed8eb-bb0e-4b7f-946d-00d9f5ab45ca'	System	09 Oct 2020 01:13:25
User entered 'Yes (Y)'	System	09 Oct 2020 01:13:25

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:13:07', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b9fed8eb-bb0e-4b7f-946d-00d9f5ab45ca'	System	09 Oct 2020 01:13:25
User entered '97.2'	System	09 Oct 2020 01:13:25

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:13:13', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b9fed8eb-bb0e-4b7f-946d-00d9f5ab45ca'	System	09 Oct 2020 01:13:25
User entered 'No (N)'	System	09 Oct 2020 01:13:25

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:13:22', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b9fed8eb-bb0e-4b7f-946d-00d9f5ab45ca'	System	09 Oct 2020 01:13:25
User entered '08 Oct 2020 21:13'	System	09 Oct 2020 01:13:25

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 14:02'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 2'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:04', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49b691a1-0d23-48b6-8503-0e290c1245b4'	System	09 Oct 2020 21:11:37
User entered 'Yes (Y)'	System	09 Oct 2020 21:11:37

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:14', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49b691a1-0d23-48b6-8503-0e290c1245b4'	System	09 Oct 2020 21:11:37
User entered '98.6'	System	09 Oct 2020 21:11:37

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:20', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49b691a1-0d23-48b6-8503-0e290c1245b4'	System	09 Oct 2020 21:11:37
User entered 'No (N)'	System	09 Oct 2020 21:11:37

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:31', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49b691a1-0d23-48b6-8503-0e290c1245b4'	System	09 Oct 2020 21:11:37
User entered '09 Oct 2020 17:11'	System	09 Oct 2020 21:11:37

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 3'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '583beff2-56b5-41c7-a3f3-a936bbb9e8a9'	System	11 Oct 2020 03:07:17
User entered 'Yes (Y)'	System	11 Oct 2020 03:07:17

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:06:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '583beff2-56b5-41c7-a3f3-a936bbb9e8a9'	System	11 Oct 2020 03:07:17
User entered '98.4'	System	11 Oct 2020 03:07:17

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:06:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '583beff2-56b5-41c7-a3f3-a936bbb9e8a9'	System	11 Oct 2020 03:07:17
User entered 'No (N)'	System	11 Oct 2020 03:07:17

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:13', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '583beff2-56b5-41c7-a3f3-a936bbb9e8a9'	System	11 Oct 2020 03:07:17
User entered '10 Oct 2020 23:07'	System	11 Oct 2020 03:07:17

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 4'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:03:20', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5afbf8f2-f7e1-416a-a106-66ad23d0f56b'	System	11 Oct 2020 21:04:20
User entered 'Yes (Y)'	System	11 Oct 2020 21:04:20

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5afbf8f2-f7e1-416a-a106-66ad23d0f56b'	System	11 Oct 2020 21:04:20
User entered '98.4'	System	11 Oct 2020 21:04:20

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5afbf8f2-f7e1-416a-a106-66ad23d0f56b'	System	11 Oct 2020 21:04:20
User entered 'No (N)'	System	11 Oct 2020 21:04:20

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:18', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5afbf8f2-f7e1-416a-a106-66ad23d0f56b'	System	11 Oct 2020 21:04:20
User entered '11 Oct 2020 17:04'	System	11 Oct 2020 21:04:20

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 5'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:12:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd40b3347-ac0b-4a47-bcf6-ebddcfe0e979'	System	12 Oct 2020 23:12:58
User entered 'Yes (Y)'	System	12 Oct 2020 23:12:58



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:12:44', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd40b3347-ac0b-4a47-bcf6-ebddcfe0e979'	System	12 Oct 2020 23:12:58
User entered '97.4'	System	12 Oct 2020 23:12:58

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:12:49', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd40b3347-ac0b-4a47-bcf6-ebddcfe0e979'	System	12 Oct 2020 23:12:58
User entered 'No (N)'	System	12 Oct 2020 23:12:58

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:12:55', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd40b3347-ac0b-4a47-bcf6-ebddcfe0e979'	System	12 Oct 2020 23:12:58
User entered '12 Oct 2020 19:12'	System	12 Oct 2020 23:12:58

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 6'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:32:47', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '72bf8ba3-a383-4071-910f-a4c8054376ca'	System	13 Oct 2020 22:33:13
User entered 'Yes (Y)'	System	13 Oct 2020 22:33:13

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:32:56', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '72bf8ba3-a383-4071-910f-a4c8054376ca' User entered '97.7'	System	13 Oct 2020 22:33:13
	System	13 Oct 2020 22:33:13



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:04', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '72bf8ba3-a383-4071-910f-a4c8054376ca'	System	13 Oct 2020 22:33:13
User entered 'No (N)'	System	13 Oct 2020 22:33:13

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:10', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '72bf8ba3-a383-4071-910f-a4c8054376ca' User entered '13 Oct 2020 18:33'	System	13 Oct 2020 22:33:13
	System	13 Oct 2020 22:33:13

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 7'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:09', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '40ebb42d-4e29-4759-8e61-4fddb57d5403'	System	15 Oct 2020 01:51:32
User entered 'Yes (Y)'	System	15 Oct 2020 01:51:32

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:18', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '40ebb42d-4e29-4759-8e61-4fddb57d5403'	System	15 Oct 2020 01:51:32
User entered '97.4'	System	15 Oct 2020 01:51:32

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:23', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '40ebb42d-4e29-4759-8e61-4fddb57d5403'	System	15 Oct 2020 01:51:32
User entered 'No (N)'	System	15 Oct 2020 01:51:32



US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '40ebb42d-4e29-4759-8e61-4fddb57d5403'	System	15 Oct 2020 01:51:32
User entered '14 Oct 2020 21:51'	System	15 Oct 2020 01:51:32

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:39:16', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ff638718-074e-4393-bd78-65024913b990'	System	08 Oct 2020 14:39:51
User entered 'None (1)'	System	08 Oct 2020 14:39:51

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:39:21', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ff638718-074e-4393-bd78-65024913b990'	System	08 Oct 2020 14:39:51
User entered 'No (N)'	System	08 Oct 2020 14:39:51

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:39:30', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ff638718-074e-4393-bd78-65024913b990'	System	08 Oct 2020 14:39:51
User entered 'No (N)'	System	08 Oct 2020 14:39:51

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:39:41', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ff638718-074e-4393-bd78-65024913b990'	System	08 Oct 2020 14:39:51
User entered 'None (1)'	System	08 Oct 2020 14:39:51



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:39:49', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ff638718-074e-4393-bd78-65024913b990'	System	08 Oct 2020 14:39:51
User entered '08 Oct 2020 10:39'	System	08 Oct 2020 14:39:51

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 10:37'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 13:07'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:10', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b5205722-f350-4f5b-b78c-4df637db3a74'	System	09 Oct 2020 01:14:38
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 01:14:38

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:13:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b5205722-f350-4f5b-b78c-4df637db3a74'	System	09 Oct 2020 01:14:38
User entered 'No (N)'	System	09 Oct 2020 01:14:38

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:15', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b5205722-f350-4f5b-b78c-4df637db3a74'	System	09 Oct 2020 01:14:38
User entered 'No (N)'	System	09 Oct 2020 01:14:38

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:23', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b5205722-f350-4f5b-b78c-4df637db3a74'	System	09 Oct 2020 01:14:38
User entered 'None (1)'	System	09 Oct 2020 01:14:38



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:36', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b5205722-f350-4f5b-b78c-4df637db3a74'	System	09 Oct 2020 01:14:38
User entered '08 Oct 2020 21:14'	System	09 Oct 2020 01:14:38

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 14:02'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 2'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f12b6b7a-d1ea-4578-903a-f31a1745b753'	System	09 Oct 2020 21:12:19
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 21:12:19

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f12b6b7a-d1ea-4578-903a-f31a1745b753'	System	09 Oct 2020 21:12:19
User entered 'No (N)'	System	09 Oct 2020 21:12:19

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:11:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f12b6b7a-d1ea-4578-903a-f31a1745b753'	System	09 Oct 2020 21:12:19
User entered 'No (N)'	System	09 Oct 2020 21:12:19

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:01', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f12b6b7a-d1ea-4578-903a-f31a1745b753'	System	09 Oct 2020 21:12:19
User entered 'None (1)'	System	09 Oct 2020 21:12:19



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'f12b6b7a-d1ea-4578-903a-f31a1745b753'	System	09 Oct 2020 21:12:19
User entered '09 Oct 2020 17:12'	System	09 Oct 2020 21:12:19

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 3'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5e6bfe68-fa7e-4110-b943-9771e18480e9'	System	11 Oct 2020 03:07:50
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 03:07:50

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5e6bfe68-fa7e-4110-b943-9771e18480e9'	System	11 Oct 2020 03:07:50
User entered 'No (N)'	System	11 Oct 2020 03:07:50

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5e6bfe68-fa7e-4110-b943-9771e18480e9'	System	11 Oct 2020 03:07:50
User entered 'No (N)'	System	11 Oct 2020 03:07:50

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5e6bfe68-fa7e-4110-b943-9771e18480e9'	System	11 Oct 2020 03:07:50
User entered 'None (1)'	System	11 Oct 2020 03:07:50



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5e6bfe68-fa7e-4110-b943-9771e18480e9'	System	11 Oct 2020 03:07:50
User entered '10 Oct 2020 23:07'	System	11 Oct 2020 03:07:50

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 4'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:25', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '9a9d1bc4-0400-4ca0-a2bd-95f76533dfaf'	System	11 Oct 2020 21:04:49
User entered 'None (1)'	System	11 Oct 2020 21:04:49

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '9a9d1bc4-0400-4ca0-a2bd-95f76533dfaf'	System	11 Oct 2020 21:04:49
User entered 'No (N)'	System	11 Oct 2020 21:04:49

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '9a9d1bc4-0400-4ca0-a2bd-95f76533dfaf'	System	11 Oct 2020 21:04:49
User entered 'No (N)'	System	11 Oct 2020 21:04:49

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:39', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '9a9d1bc4-0400-4ca0-a2bd-95f76533dfaf'	System	11 Oct 2020 21:04:49
User entered 'None (1)'	System	11 Oct 2020 21:04:49



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:45', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '9a9d1bc4-0400-4ca0-a2bd-95f76533dfaf'	System	11 Oct 2020 21:04:49
User entered '11 Oct 2020 17:04'	System	11 Oct 2020 21:04:49

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 5'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:01', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7721745c-b97b-4ac6-8b51-72ea13798686'	System	12 Oct 2020 23:13:30
User entered 'None (1)'	System	12 Oct 2020 23:13:30

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7721745c-b97b-4ac6-8b51-72ea13798686'	System	12 Oct 2020 23:13:30
User entered 'No (N)'	System	12 Oct 2020 23:13:30

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:09', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7721745c-b97b-4ac6-8b51-72ea13798686'	System	12 Oct 2020 23:13:30
User entered 'No (N)'	System	12 Oct 2020 23:13:30

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:16', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7721745c-b97b-4ac6-8b51-72ea13798686'	System	12 Oct 2020 23:13:30
User entered 'None (1)'	System	12 Oct 2020 23:13:30



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:23', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7721745c-b97b-4ac6-8b51-72ea13798686'	System	12 Oct 2020 23:13:30
User entered '12 Oct 2020 19:13'	System	12 Oct 2020 23:13:30

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 6'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3031e5de-34f0-482b-ae95-b7086002287a'	System	13 Oct 2020 22:33:37
User entered 'None (1)'	System	13 Oct 2020 22:33:37

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:21', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3031e5de-34f0-482b-ae95-b7086002287a'	System	13 Oct 2020 22:33:37
User entered 'No (N)'	System	13 Oct 2020 22:33:37

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:25', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3031e5de-34f0-482b-ae95-b7086002287a'	System	13 Oct 2020 22:33:37
User entered 'No (N)'	System	13 Oct 2020 22:33:37

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:29', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3031e5de-34f0-482b-ae95-b7086002287a'	System	13 Oct 2020 22:33:37
User entered 'None (1)'	System	13 Oct 2020 22:33:37



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:34', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3031e5de-34f0-482b-ae95-b7086002287a' User entered '13 Oct 2020 18:33'	System	13 Oct 2020 22:33:37
	System	13 Oct 2020 22:33:37

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 7'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:38', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0616a23e-125c-4cfb-b364-f46e28e97fab'	System	15 Oct 2020 01:52:06
User entered 'None (1)'	System	15 Oct 2020 01:52:06

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0616a23e-125c-4cfb-b364-f46e28e97fab'	System	15 Oct 2020 01:52:06
User entered 'No (N)'	System	15 Oct 2020 01:52:06

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0616a23e-125c-4cfb-b364-f46e28e97fab'	System	15 Oct 2020 01:52:06
User entered 'No (N)'	System	15 Oct 2020 01:52:06

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:51:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0616a23e-125c-4cfb-b364-f46e28e97fab'	System	15 Oct 2020 01:52:06
User entered 'None (1)'	System	15 Oct 2020 01:52:06



US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:01', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0616a23e-125c-4cfb-b364-f46e28e97fab'	System	15 Oct 2020 01:52:06
User entered '14 Oct 2020 21:52'	System	15 Oct 2020 01:52:06

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:13', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:20', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:26', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'None (0)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:40:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered 'No (N)'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T10:41:02', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '98c5339a-cf00-4009-a9d3-207e2e6781bf'	System	08 Oct 2020 14:41:07
User entered '08 Oct 2020 10:41'	System	08 Oct 2020 14:41:07

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 10:37'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 13:07'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:45', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:49', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:14:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:15:02', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:15:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'None (0)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:15:16', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered 'No (N)'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-08T21:15:24', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'e7e6239f-584f-4c9d-9fa6-d2c57b75c5ec'	System	09 Oct 2020 01:15:28
User entered '08 Oct 2020 21:15'	System	09 Oct 2020 01:15:28

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '08 Oct 2020 14:02'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 2'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:26', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:46', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:50', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'None (0)'	System	09 Oct 2020 21:13:14



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:12:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered 'No (N)'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-09T17:13:11', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '09e3cbd7-29f9-4ab4-8e48-2482164a864d'	System	09 Oct 2020 21:13:14
User entered '09 Oct 2020 17:13'	System	09 Oct 2020 21:13:14

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 3'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:07:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:01', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:10', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:13', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'None (0)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:19', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered 'No (N)'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-10T23:08:25', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '452b3164-80d2-4ecb-947b-b0888776eaca'	System	11 Oct 2020 03:08:27
User entered '10 Oct 2020 23:08'	System	11 Oct 2020 03:08:27

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 4'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:04:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:02', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:10', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:14', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'None (0)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:21', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered 'No (N)'	System	11 Oct 2020 21:05:30

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-11T17:05:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b7471171-5998-400e-8e20-288a418df47a'	System	11 Oct 2020 21:05:30
User entered '11 Oct 2020 17:05'	System	11 Oct 2020 21:05:30



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 5'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:29', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:33', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:47', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:50', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'None (0)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:13:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered 'No (N)'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-12T19:14:09', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '78d53c79-fb96-42ec-909d-dc8ffec552c0'	System	12 Oct 2020 23:14:13
User entered '12 Oct 2020 19:14'	System	12 Oct 2020 23:14:13

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 6'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:40', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:43', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:47', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:33:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:34:01', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'None (0)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:34:08', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered 'No (N)'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-13T18:34:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '5c87f4d2-f153-40c4-af31-1ef8ea7b17dd'	System	13 Oct 2020 22:34:19
User entered '13 Oct 2020 18:34'	System	13 Oct 2020 22:34:19

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:22:10



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	08 Oct 2020 14:22:10
User entered 'Day 7'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:09', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:22', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:27', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:31', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'None (0)'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:48', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered 'No (N)'	System	15 Oct 2020 01:52:58



US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-10-14T21:52:56', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1d8316dd-82b2-498f-9f0c-703aac982000'	System	15 Oct 2020 01:52:58
User entered '14 Oct 2020 21:52'	System	15 Oct 2020 01:52:58

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:22:10

US3842027

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:22:10

US3842027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:05:31
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 20:36:04

**US3842027**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:02**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:05:31
User entered '15 Oct 2020'	Christie Lyn Costanza (b) (4)	19 Oct 2020 20:36:04

US3842027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:05:31
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza (b) (4)	19 Oct 2020 20:36:04

US3842027

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:05:31
User entered empty.	Christie Lyn Costanza (b) (4)	19 Oct 2020 20:36:04

US3842027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:22:03
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	19 Oct 2020 20:36:07
	Christie Lyn Costanza	
	(b) (4)	



US3842027

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'I'	System	19 Oct 2020 20:36:07

US3842027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:39:48
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:21:58

US3842027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:39:48
User entered '23 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:21:58

US3842027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:39:48
User entered 'Contact Made (CONTACT MADE)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:21:58

US3842027

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:39:48
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:21:58

US3842027

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:39:54
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:06

US3842027

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'I'	System	05 Nov 2020 15:22:06

US3842027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:40:41
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:24



US3842027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:40:41
User entered '29 Oct 2020'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:24

US3842027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:40:41
User entered 'Contact Made (CONTACT MADE)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:24

US3842027

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:40:41
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:24

US3842027

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:40:52
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:31

US3842027

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'I'	System	05 Nov 2020 15:22:31

US3842027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:41:42
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:53

US3842027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:41:42
User entered '05 Nov 2020'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:53

US3842027

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:41:42
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:22:53



**US3842027**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'VISIT3'	System	05 Nov 2020 15:22:53

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '05 Nov 2020'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '09:36'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '05 Nov 2020 09:36'	System	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '97.8' F	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered 'Oral (Oral)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17



US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '98'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'bpm'	System	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '16'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'breaths/min'	System	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '131'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:15
User entered '60'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:25:17

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'mmHg'	System	05 Nov 2020 15:25:17



US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18

US3842027

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18

US3842027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:22
User entered 'No (N)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:34:13

US3842027

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:22
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:34:13

US3842027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:49
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:34:54

US3842027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:49
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:05:47
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' answered with 'Sample collection date 05NOV2020. confirmed per GCL immuno 1-10 received 06NOV2020 and 11-14 11NOV2020.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	24 Nov 2020 15:07:53
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 05NOV2020. However, collection date is missing in GCL. Please confirm if 05NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:01:18
User entered '05 Nov 2020'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:34:54

US3842027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:49
User entered '9:50'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:34:54

US3842027

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered '05 Nov 2020 9:50'	System	05 Nov 2020 15:34:54



US3842027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 21:42:55
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	05 Nov 2020 15:35:10

US3842027

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:18
User entered 'I'	System	05 Nov 2020 15:35:10

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 64'	System	10 Sep 2020 17:44:34

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-10T14:59:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ed4063c0-90d6-4355-831f-24bdb97893be'	System	10 Nov 2020 19:59:57
User entered 'No (N)'	System	10 Nov 2020 19:59:57

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-10T14:59:41', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ed4063c0-90d6-4355-831f-24bdb97893be'	System	10 Nov 2020 19:59:57
User entered 'No (N)'	System	10 Nov 2020 19:59:57

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-10T14:59:53', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'ed4063c0-90d6-4355-831f-24bdb97893be'	System	10 Nov 2020 19:59:57
User entered '10 Nov 2020 14:59:53'	System	10 Nov 2020 19:59:57

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 17:44:34

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 17:44:34



US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered 'Day 71'	System	10 Sep 2020 17:44:34

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-17T12:02:04', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3e43a525-1ad4-4a08-a4a8-5fe042f85f39'	System	17 Nov 2020 17:03:33
User entered 'No (N)'	System	17 Nov 2020 17:03:33

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-17T12:02:19', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3e43a525-1ad4-4a08-a4a8-5fe042f85f39'	System	17 Nov 2020 17:03:33
User entered 'No (N)'	System	17 Nov 2020 17:03:33

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-17T12:02:46', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '3e43a525-1ad4-4a08-a4a8-5fe042f85f39' User entered '17 Nov 2020 12:02:46'	System	17 Nov 2020 17:03:33
	System	17 Nov 2020 17:03:33

US3842027

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 17:44:34

US3842027

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:00:03
Data entry locked.	System	10 Sep 2020 17:44:34
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 17:44:34

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-11-21T15:17:44', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2deb298e-9a51-4bc6-a84e-7be49f29784e'	System	21 Nov 2020 20:18:20
User entered 'No (N)'	System	21 Nov 2020 20:18:20



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-11-21T15:18:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2deb298e-9a51-4bc6-a84e-7be49f29784e'	System	21 Nov 2020 20:18:20
User entered 'No (N)'	System	21 Nov 2020 20:18:20

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-21T15:18:16', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2deb298e-9a51-4bc6-a84e-7be49f29784e'	System	21 Nov 2020 20:18:20
User entered '21 Nov 2020 15:18:16'	System	21 Nov 2020 20:18:20

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-11-29T09:15:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b390f344-2013-41d0-b08c-8f9a63e98bbc'	System	29 Nov 2020 14:15:46
User entered 'No (N)'	System	29 Nov 2020 14:15:46

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-11-29T09:15:31', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b390f344-2013-41d0-b08c-8f9a63e98bbc'	System	29 Nov 2020 14:15:46
User entered 'No (N)'	System	29 Nov 2020 14:15:46

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-11-29T09:15:41', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'b390f344-2013-41d0-b08c-8f9a63e98bbc'	System	29 Nov 2020 14:15:46
User entered '29 Nov 2020 09:15:41'	System	29 Nov 2020 14:15:46



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-12-07T09:14:55', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '767783ff-9b0b-4a14-9253-6badf57c7245'	System	07 Dec 2020 14:15:11
User entered 'No (N)'	System	07 Dec 2020 14:15:11

US3842027

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-12-07T09:15:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '767783ff-9b0b-4a14-9253-6badf57c7245'	System	07 Dec 2020 14:15:11
User entered 'No (N)'	System	07 Dec 2020 14:15:11

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-12-07T09:15:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '767783ff-9b0b-4a14-9253-6badf57c7245'	System	07 Dec 2020 14:15:11
User entered '07 Dec 2020 09:15:05'	System	07 Dec 2020 14:15:11

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-12-12T12:18:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '99360ac5-e649-405d-84e3-622ca298ef64'	System	12 Dec 2020 17:19:08
User entered 'No (N)'	System	12 Dec 2020 17:19:08

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-12-12T12:18:57', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '99360ac5-e649-405d-84e3-622ca298ef64'	System	12 Dec 2020 17:19:08
User entered 'No (N)'	System	12 Dec 2020 17:19:08

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-12-12T12:19:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '99360ac5-e649-405d-84e3-622ca298ef64'	System	12 Dec 2020 17:19:08
User entered '12 Dec 2020 12:19:05'	System	12 Dec 2020 17:19:08

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-12-19T17:20:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered 'Yes (Y)'	System	19 Dec 2020 22:21:48



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-12-19T17:20:44', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered 'No (N)'	System	19 Dec 2020 22:21:48

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

[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 (9b0aa7442d345149)', Time: '2020-12-19T17:20:54', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered 'No (N)'	System	19 Dec 2020 22:21:48

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-12-19T17:21:05', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered 'Yes (Y)'	System	19 Dec 2020 22:21:48

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Please 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 (9b0aa7442d345149)', Time: '2020-12-19T17:21:31', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 22:21:48

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-12-19T17:21:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2ad1434e-749d-464a-bd9d-2ae321528664'	System	19 Dec 2020 22:21:48
User entered '19 Dec 2020 17:21:37'	System	19 Dec 2020 22:21:48

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2020-12-26T12:27:36', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1543c371-aeac-45f2-a84f-f92f25d217e3'	System	26 Dec 2020 17:28:02
User entered 'No (N)'	System	26 Dec 2020 17:28:02

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2020-12-26T12:27:50', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1543c371-aeac-45f2-a84f-f92f25d217e3'	System	26 Dec 2020 17:28:02
User entered 'No (N)'	System	26 Dec 2020 17:28:02

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2020-12-26T12:28:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1543c371-aeac-45f2-a84f-f92f25d217e3'	System	26 Dec 2020 17:28:02
User entered '26 Dec 2020 12:28:00'	System	26 Dec 2020 17:28:02

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:00:47

US3842027

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-01-04T23:11:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fe7ca6ae-5993-4dac-a3b5-5ba0fdd8973c'	System	05 Jan 2021 04:11:49
User entered 'No (N)'	System	05 Jan 2021 04:11:49

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-01-04T23:11:41', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fe7ca6ae-5993-4dac-a3b5-5ba0fdd8973c'	System	05 Jan 2021 04:11:49
User entered 'No (N)'	System	05 Jan 2021 04:11:49



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-01-04T23:11:46', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fe7ca6ae-5993-4dac-a3b5-5ba0fdd8973c'	System	05 Jan 2021 04:11:49
User entered '04 Jan 2021 23:11:46'	System	05 Jan 2021 04:11:49

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-01-09T09:09:24', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '58a37865-404a-4c4d-863f-f79c55cd032d'	System	09 Jan 2021 14:09:37
User entered 'No (N)'	System	09 Jan 2021 14:09:37

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-01-09T09:09:31', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '58a37865-404a-4c4d-863f-f79c55cd032d'	System	09 Jan 2021 14:09:37
User entered 'No (N)'	System	09 Jan 2021 14:09:37

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-01-09T09:09:35', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '58a37865-404a-4c4d-863f-f79c55cd032d'	System	09 Jan 2021 14:09:37
User entered '09 Jan 2021 09:09:35'	System	09 Jan 2021 14:09:37

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-01-17T09:28:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0f80075d-92e6-4574-82fe-6538daed415d'	System	17 Jan 2021 14:29:17
User entered 'No (N)'	System	17 Jan 2021 14:29:17

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-01-17T09:29:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0f80075d-92e6-4574-82fe-6538daed415d'	System	17 Jan 2021 14:29:17
User entered 'No (N)'	System	17 Jan 2021 14:29:17

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-01-17T09:29:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '0f80075d-92e6-4574-82fe-6538daed415d'	System	17 Jan 2021 14:29:17
User entered '17 Jan 2021 09:29:12'	System	17 Jan 2021 14:29:17

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-01-24T06:53:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dc9f0dda-b5cd-4009-8458-e307577ae7e2'	System	24 Jan 2021 11:53:31
User entered 'No (N)'	System	24 Jan 2021 11:53:31

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-01-24T06:53:17', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dc9f0dda-b5cd-4009-8458-e307577ae7e2'	System	24 Jan 2021 11:53:31
User entered 'No (N)'	System	24 Jan 2021 11:53:31

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-01-24T06:53:28', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'dc9f0dda-b5cd-4009-8458-e307577ae7e2'	System	24 Jan 2021 11:53:31
User entered '24 Jan 2021 06:53:28'	System	24 Jan 2021 11:53:31

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-01-30T17:40:32', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7c835799-1c14-4c33-b066-86d236c7c86b'	System	30 Jan 2021 22:40:45
User entered 'No (N)'	System	30 Jan 2021 22:40:45

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-01-30T17:40:36', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7c835799-1c14-4c33-b066-86d236c7c86b'	System	30 Jan 2021 22:40:45
User entered 'No (N)'	System	30 Jan 2021 22:40:45



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-01-30T17:40:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '7c835799-1c14-4c33-b066-86d236c7c86b'	System	30 Jan 2021 22:40:45
User entered '30 Jan 2021 17:40:42'	System	30 Jan 2021 22:40:45

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-02-08T12:28:37', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '65d0b89f-11b9-4b34-9a08-b1f493ef167c'	System	08 Feb 2021 17:28:50
User entered 'No (N)'	System	08 Feb 2021 17:28:50

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-02-08T12:28:42', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '65d0b89f-11b9-4b34-9a08-b1f493ef167c'	System	08 Feb 2021 17:28:50
User entered 'No (N)'	System	08 Feb 2021 17:28:50

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-02-08T12:28:47', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '65d0b89f-11b9-4b34-9a08-b1f493ef167c'	System	08 Feb 2021 17:28:50
User entered '08 Feb 2021 12:28:47'	System	08 Feb 2021 17:28:50

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-02-15T07:21:47', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '6ef3734d-b0fc-46e4-baf5-7c1bae8d9d2e'	System	15 Feb 2021 12:21:58
User entered 'No (N)'	System	15 Feb 2021 12:21:58

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-02-15T07:21:51', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '6ef3734d-b0fc-46e4-baf5-7c1bae8d9d2e'	System	15 Feb 2021 12:21:58
User entered 'No (N)'	System	15 Feb 2021 12:21:58

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-02-15T07:21:55', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '6ef3734d-b0fc-46e4-baf5-7c1bae8d9d2e'	System	15 Feb 2021 12:21:58
User entered '15 Feb 2021 07:21:55'	System	15 Feb 2021 12:21:58

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-02-20T11:00:58', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49e84778-b8bc-484f-b14e-cebc45be5a37'	System	20 Feb 2021 16:01:17
User entered 'No (N)'	System	20 Feb 2021 16:01:17

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-02-20T11:01:06', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49e84778-b8bc-484f-b14e-cebc45be5a37'	System	20 Feb 2021 16:01:17
User entered 'No (N)'	System	20 Feb 2021 16:01:17

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-02-20T11:01:12', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '49e84778-b8bc-484f-b14e-cebc45be5a37'	System	20 Feb 2021 16:01:17
User entered '20 Feb 2021 11:01:12'	System	20 Feb 2021 16:01:17

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-03-01T14:50:45-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '007266c0-f80f-4145-adc6-c081c466fbd6'	System	01 Mar 2021 19:50:56
User entered 'No (N)'	System	01 Mar 2021 19:50:56

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-03-01T14:50:49-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '007266c0-f80f-4145-adc6-c081c466fbd6'	System	01 Mar 2021 19:50:56
User entered 'No (N)'	System	01 Mar 2021 19:50:56



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-01T14:50:54-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '007266c0-f80f-4145-adc6-c081c466fbd6'	System	01 Mar 2021 19:50:56
User entered '01 Mar 2021 14:50:54'	System	01 Mar 2021 19:50:56

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-03-06T10:36:30-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '41ef34a2-7af7-4dcc-b8ac-84f3d6b54e47'	System	06 Mar 2021 15:37:25
User entered 'No (N)'	System	06 Mar 2021 15:37:25

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-03-06T10:36:36-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '41ef34a2-7af7-4dcc-b8ac-84f3d6b54e47'	System	06 Mar 2021 15:37:25
User entered 'No (N)'	System	06 Mar 2021 15:37:25

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-06T10:36:42-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '41ef34a2-7af7-4dcc-b8ac-84f3d6b54e47'	System	06 Mar 2021 15:37:25
User entered '06 Mar 2021 10:36:42'	System	06 Mar 2021 15:37:25

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-03-24T10:16:07-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'c35d8a3a-8e62-45e1-8373-e3c7d46dc43c'	System	24 Mar 2021 14:16:16
User entered 'No (N)'	System	24 Mar 2021 14:16:16

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-03-24T10:16:10-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'c35d8a3a-8e62-45e1-8373-e3c7d46dc43c'	System	24 Mar 2021 14:16:16
User entered 'No (N)'	System	24 Mar 2021 14:16:16

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-24T10:16:13-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'c35d8a3a-8e62-45e1-8373-e3c7d46dc43c'	System	24 Mar 2021 14:16:16
User entered '24 Mar 2021 10:16:13'	System	24 Mar 2021 14:16:16



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-03-27T13:01:55-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fdac84e3-07f2-4bf1-a8da-2e9b8b4d28b8'	System	27 Mar 2021 17:03:33
User entered 'No (N)'	System	27 Mar 2021 17:03:33

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-03-27T13:02:03-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fdac84e3-07f2-4bf1-a8da-2e9b8b4d28b8'	System	27 Mar 2021 17:03:33
User entered 'No (N)'	System	27 Mar 2021 17:03:33

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-27T13:02:14-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'fdac84e3-07f2-4bf1-a8da-2e9b8b4d28b8'	System	27 Mar 2021 17:03:33
User entered '27 Mar 2021 13:02:14'	System	27 Mar 2021 17:03:33

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-04-06T13:51:56-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1130c376-c113-4d8d-b208-a7ffe12091e8'	System	06 Apr 2021 17:52:06
User entered 'No (N)'	System	06 Apr 2021 17:52:06

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-04-06T13:51:59-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1130c376-c113-4d8d-b208-a7ffe12091e8'	System	06 Apr 2021 17:52:06
User entered 'No (N)'	System	06 Apr 2021 17:52:06

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-04-06T13:52:03-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '1130c376-c113-4d8d-b208-a7ffe12091e8'	System	06 Apr 2021 17:52:06
User entered '06 Apr 2021 13:52:03'	System	06 Apr 2021 17:52:06

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-04-14T10:50:01-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2d07eb2d-9fa5-4686-bdfd-08cd3c8a4334'	System	14 Apr 2021 17:20:14
User entered 'No (N)'	System	14 Apr 2021 17:20:14



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-04-14T10:50:04-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2d07eb2d-9fa5-4686-bdfd-08cd3c8a4334'	System	14 Apr 2021 17:20:14
User entered 'No (N)'	System	14 Apr 2021 17:20:14

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-04-14T10:50:08-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '2d07eb2d-9fa5-4686-bdfd-08cd3c8a4334'	System	14 Apr 2021 17:20:14
User entered '14 Apr 2021 10:50:08'	System	14 Apr 2021 17:20:14

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-04-17T09:07:41-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '986fe39f-2441-46e0-a092-88be1f47525e'	System	17 Apr 2021 13:07:53
User entered 'No (N)'	System	17 Apr 2021 13:07:53

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-04-17T09:07:46-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '986fe39f-2441-46e0-a092-88be1f47525e'	System	17 Apr 2021 13:07:53
User entered 'No (N)'	System	17 Apr 2021 13:07:53

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-04-17T09:07:49-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: '986fe39f-2441-46e0-a092-88be1f47525e'	System	17 Apr 2021 13:07:53
User entered '17 Apr 2021 09:07:49'	System	17 Apr 2021 13:07:53



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[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 (9b0aa7442d345149)', Time: '2021-04-27T08:29:06-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd6684f35-2bfa-40a3-ba52-24f881c2e21e'	System	29 Apr 2021 00:00:16
User entered 'No (N)'	System	29 Apr 2021 00:00:16

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

Have you been exposed to someone with 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 (9b0aa7442d345149)', Time: '2021-04-27T08:29:08-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd6684f35-2bfa-40a3-ba52-24f881c2e21e'	System	29 Apr 2021 00:00:16
User entered 'No (N)'	System	29 Apr 2021 00:00:16

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-04-27T08:29:12-04:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'd6684f35-2bfa-40a3-ba52-24f881c2e21e'	System	29 Apr 2021 00:00:16
User entered '27 Apr 2021 08:29:12'	System	29 Apr 2021 00:00:16

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:00:47

US3842027

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:00:47



US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:00:47

US3842027

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:00:47



**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:00:47



US3842027

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:02

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:00:47

**US3842027**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:02**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:00:47
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:00:47

US3842027

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:02:02**

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)	25 Apr 2021 19:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-01T14:50:19-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'eb0b6fe8-53ef-41da-96da-d16b6710adcc'	System	01 Mar 2021 19:50:37
User entered 'No (N)'	System	01 Mar 2021 19:50:37

US3842027

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:02:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9b0aa7442d345149)', Time: '2021-03-01T14:50:33-05:00', User OID: 'PatientReportedOutcome (US3842027)', ODM File OID: 'eb0b6fe8-53ef-41da-96da-d16b6710adcc'	System	01 Mar 2021 19:50:37
User entered '01 Mar 2021 14:50:33'	System	01 Mar 2021 19:50:37

**US3842027**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:02**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:14
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 15:57:51
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:14
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '30 Nov 2020'	(b) (4)	13 Jan 2021 15:57:51
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:14
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	13 Jan 2021 15:57:51



US3842027

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:14
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	13 Jan 2021 15:57:51
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 15:57:55
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:25:16
User entered 'I'	System	13 Jan 2021 15:57:55

US3842027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:21:21
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-query: Previous query response indicates, "Thank you - unsure as to what this query is for the safety call?", however, the Immunogenicity Assessment sample is still missing in EDC. Please update the Participant Decision Visit / OL-D1 folder, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:40:51
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-query: Previous query response indicates, "Thank you - unsure as to what this query is for the safety call?", however, the Immunogenicity Assessment sample is still missing in EDC. Please update the Participant Decision Visit / OL-D1 folder, as appropriate. ' answered with 'information added to OL D1' (Site from DM).	(b) (4)	05 Feb 2021 23:51:12
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Re-query: Previous query response indicates, "Thank you - unsure as to what this query is for the safety call?", however, the Immunogenicity Assessment sample is still missing in EDC. Please update the Participant Decision Visit / OL-D1 folder, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 20:01:00
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 20:01:00

US3842027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' answered with 'Thank you - unsure as to what this query is for the safety call?' (Site from DM).	Christie Lyn Costanza (b) (4)	05 Feb 2021 00:00:10
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 13JAN2021 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:57:04
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	13 Jan 2021 15:58:25

**US3842027**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:02**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:21:21
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '03 Jan 2021'	(b) (4) Christie Lyn Costanza (b) (4)	13 Jan 2021 15:58:25

US3842027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:21:21
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	13 Jan 2021 15:58:25

US3842027

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:21:21
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	13 Jan 2021 15:58:25
	Christie Lyn Costanza	
	(b) (4)	



US3842027

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:21:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	13 Jan 2021 15:58:29

US3842027

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
User entered 'I'	System	13 Jan 2021 15:58:29

US3842027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:22:03
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 01:10:23
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:22:03
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '04 Feb 2021'	(b) (4)	05 Feb 2021 01:10:23
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:22:03
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 01:10:23

US3842027

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:22:03
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered empty.	(b) (4)	05 Feb 2021 01:10:23
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:22:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 01:10:26

US3842027

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
User entered 'I'	System	05 Feb 2021 01:10:26



US3842027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:11:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 01:35:15
	Christie Lyn Costanza	
	(b) (4)	

**US3842027**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:02**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:11:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '10 Mar 2021'	(b) (4) Christie Lyn Costanza (b) (4)	11 Mar 2021 01:35:15

US3842027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:11:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza (b) (4)	11 Mar 2021 01:35:15

US3842027

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:02:02

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:11:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	11 Mar 2021 01:35:15
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:12:03
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	11 Mar 2021 01:35:19

US3842027

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:33:12
User entered 'I'	System	11 Mar 2021 01:35:19

US3842027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	08 Apr 2021 20:03:38
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '08 Apr 2021'	Mario Portilla (b) (4)	08 Apr 2021 20:03:38
	(b) (4)	



US3842027

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Clinic (Clinic)'	Mario Portilla (b) (4)	08 Apr 2021 20:03:38
	(b) (4)	

**US3842027**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:02**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	08 Apr 2021 20:03:38

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '08 Apr 2021'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '09:07'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 09:07'	System	08 Apr 2021 20:05:33

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '98.3' F	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Oral (Oral)'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	



US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '95'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

**US3842027**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:02**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 20:05:33

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '16'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 20:05:33

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '127'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 20:05:33

US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '66'	Mario Portilla (b) (4)	08 Apr 2021 20:05:33
	(b) (4)	



US3842027

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 20:05:33

US3842027

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	08 Apr 2021 20:05:42
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	08 Apr 2021 20:05:42
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	08 Apr 2021 20:06:13
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '08 Apr 2021'	Mario Portilla (b) (4)	08 Apr 2021 20:06:13
	(b) (4)	

US3842027

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered '10:15'	Mario Portilla (b) (4)	08 Apr 2021 20:06:13
	(b) (4)	

**US3842027**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:02**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 10:15'	System	08 Apr 2021 20:06:13

US3842027

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	08 Apr 2021 20:06:22
	(b) (4)	



**US3842027**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:02**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 20:06:22

US3842027

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:02

US3842027

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13 Jan 2021'	(b) (4)	05 Feb 2021 23:50:02
	Christie Lyn Costanza	
	(b) (4)	

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

Form: Visit Date

Generated On: 10 Jun 2021 10:02:02

[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 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:44
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Clinic (Clinic)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:02

**US3842027**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:02**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 23:50:02

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13 Jan 2021'	(b) (4)	05 Feb 2021 23:50:31
	Christie Lyn Costanza	
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[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 09:58:24
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:55:53

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 23:50:31
	Christie Lyn Costanza	
	(b) (4)	



**US3842027**

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

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:02**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
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 14:55:53

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13 Jan 2021'	(b) (4)	05 Feb 2021 23:50:31
	Christie Lyn Costanza	
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:31

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:31

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:31

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:14:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'No (N)'	(b) (4)	05 Feb 2021 23:50:31
	Christie Lyn Costanza	
	(b) (4)	

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User entered empty.	System	05 Feb 2021 23:50:31

US3842027

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

Form: Unblinding

Generated On: 10 Jun 2021 10:02:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User entered empty.	System	05 Feb 2021 23:50:31



US3842027

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	05 Feb 2021 23:50:46
	Christie Lyn Costanza	
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13 Jan 2021'	(b) (4)	05 Feb 2021 23:50:46
	Christie Lyn Costanza	
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:41
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '10:18'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:46

US3842027

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User entered '13 Jan 2021 10:18'	System	05 Feb 2021 23:50:46

US3842027

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza (b) (4)	05 Feb 2021 23:50:56

US3842027

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '13 Jan 2021'	(b) (4)	05 Feb 2021 23:50:56
	Christie Lyn Costanza	
	(b) (4)	

**US3842027**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:02**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:15:50
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '09:55'	(b) (4)	05 Feb 2021 23:50:56
	Christie Lyn Costanza	
	(b) (4)	

**US3842027**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:02**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:58:24
User entered '13 Jan 2021 09:55'	System	05 Feb 2021 23:50:56



US3842027

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:02:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:15
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:25:14
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	21 Dec 2020 21:47:15

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 21:02:23
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Mario Portilla (b) (4)	19 Feb 2021 22:50:30
' answered with 'per SAE medical report participant resulted negative when tested at hospital prior to admission' (Site from DM).	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	15 Feb 2021 13:12:40
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:49:01
Data point term sent to Coder	System	22 Jan 2021 17:47:42
User entered 'Fatigue'	Mario Portilla (b) (4) (b) (4)	22 Jan 2021 17:46:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:18:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated per query' (Site from DM).	(b) (4)	
	Mario Portilla (b) (4)	26 Feb 2021 16:45:44
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	26 Feb 2021 16:45:24
	(b) (4)	
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria per protocol section 8.3.4. This AE started after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:38:12
User entered 'Yes (Y)'	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '29 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	22 Jan 2021 17:46:48
	Mario Portilla (b) (4)	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
User entered empty.	System	22 Jan 2021 17:46:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '13 Jan 2021'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	22 Jan 2021 17:46:48
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
User entered empty.	System	22 Jan 2021 17:46:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 17:47:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 17:47:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mario Portilla (b) (4)	22 Jan 2021 17:47:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 17:46:48
User entered empty.	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 17:47:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 17:47:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mario Portilla (b) (4)	22 Jan 2021 17:47:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 17:46:48
User entered empty.	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 17:47:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 17:47:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mario Portilla (b) (4)	22 Jan 2021 17:47:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 17:46:48
User entered empty.	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	23 Apr 2021 19:34:28
Signature has been broken.	Mario Portilla (b) (4)	01 Apr 2021 18:31:47
User signature succeeded.	(b) (4)	26 Feb 2021 19:02:23
User entered 'I'	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	22 Jan 2021 17:46:48



**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	22 Jan 2021 17:46:48
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
User entered '0'	System	22 Jan 2021 17:46:48

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01
User entered '0'	System	22 Jan 2021 17:46:48

US3842027

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:01

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:38:52
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:38:47
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 16:38:43
User entered 'USA-US110-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	22 Feb 2021 16:38:25

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Left Pneumothorax. If yes, please update to reflect worsening rather than recurrent as the MH condition is listed as ongoing. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 10:13:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Pneumothorax - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:55:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:55:51
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Left Pneumothorax. If yes, please update to reflect worsening rather than recurrent as the MH condition is listed as ongoing. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'UPDATED TO REFLECT WORSENING OF MH.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	15 Mar 2021 18:24:41
Data point term sent to Coder	System	15 Mar 2021 18:18:45
Coding entries removed.	Zoraida Cruz (b) (4) (b) (4)	15 Mar 2021 18:17:57
Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	15 Mar 2021 18:17:57
User entered 'WORSENING LEFT PNEUMOTHORAX' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	15 Mar 2021 18:17:57
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Left Pneumothorax. If yes, please update to reflect worsening rather than recurrent as the MH condition is listed as ongoing. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 02:52:25

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pneumothorax, LLT: Pneumothorax - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 18:05:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 18:05:59
	(b) (4)	
Data point term sent to Coder	System	19 Feb 2021 22:06:22
User entered 'Recurrent Left Pneumothorax'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '19 Dec 2020'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '23 Dec 2020'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	19 Feb 2021 22:06:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Feb 2021 22:05:28
User entered 'Yes (Y)'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '1' reason for change: Data Entry Error	(b) (4)	19 Feb 2021 22:06:34
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Feb 2021 22:06:34
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Feb 2021 22:06:34
User entered '1' reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Feb 2021 22:06:34
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Feb 2021 22:05:28
User entered '0'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '19 Dec 2020'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '23 Dec 2020'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Not Related (NOT RELATED)'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:43:51
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' answered with 'Per query, information has been updated' (Site from Safety).	Mario Portilla (b) (4)	01 Apr 2021 18:10:16
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	01 Apr 2021 18:09:20
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mario Portilla (b) (4)	01 Apr 2021 18:09:20
	(b) (4)	
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:57:38
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with the study drug from none to not applicable for the event of 'recurrent left pneumothorax'.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:42:11
Query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with the study drug from none to not applicable for the event of 'recurrent left pneumothorax'.' answered with 'reviewed and updated per query' (Site from Safety).	Malithi Desilva (b) (4) (b) (4)	19 Mar 2021 20:58:34
Signature has been broken.	Malithi Desilva (b) (4) (b) (4)	19 Mar 2021 20:58:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	19 Mar 2021 20:58:21
User opened query 'PV Query: As the last dose of study drug was given on 08 Oct 2020, please update the action taken with the study drug from none to not applicable for the event of 'recurrent left pneumothorax'.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 19:29:19
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered 'None (NONE)'	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 10:13:42
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'per Query information has been updated' (Site from DM).	Mario Portilla (b) (4)	16 Mar 2021 19:55:05
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	14 Mar 2021 02:52:37
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'I'	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures were indicated for Medical History rather than AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:08:52
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures were indicated for Medical History rather than AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'Per query, information has been updated' (Site from DM).	Mario Portilla (b) (4)	16 Mar 2021 20:04:38
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures were indicated for Medical History rather than AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 02:52:45
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'I'	Mario Portilla (b) (4)	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	19 Feb 2021 22:05:28
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	19 Feb 2021 22:07:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Feb 2021 22:07:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT US3842027 REPORTED TO STUDY RN ON 21 DEC 2020 AT 1100 VIA TEXT MESSAGE THEY WERE ADMITTED TO AN AREA HOSPITAL ON SATURDAY, 19 DEC 2020 FOR TREATMENT AND SURGICAL INTERVENTION OF A LEFT COLLAPSED LUNG (SEVERE, GRADE 3). COVID-19 TEST ON ADMISSION NEGATIVE PER PARTICIPANT. PARTICIPANT WAS SCREENED, ENROLLED AND RECEIVED FIRST INJECTION ON MRNA1273-P301 ON 10 SEP 2020; RECEIPT OF SECOND INJECTION WAS 08 OCT 2020. PARTICIPANT HAS DENIED ANY ADVERSE EVENTS SINCE ENROLLMENT. MEDICAL HISTORY SIGNIFICANT FOR LEFT COLLAPSED LUNG (DIAGNOSED MAY 2020, HOSPITALIZED FOR 6 DAYS AND DISCHARGED RESOLVED), TYPE II DIABETES (DIAGNOSED 1980), PROSTATE CANCER (DIAGNOSED 2008, RESOLVED 2013), LUNG CANCER, STAGE 1 (DIAGNOSED 2013, RESOLVED 2013), COLON CANCER (DIAGNOSED 2012, RESOLVED 2012), TRANSCATHETER AORTIC VALVE REPLACEMENT (2016), AND SLEEP APNEA (DIAGNOSED 2010). PER PARTICIPANT REPORT, THEY WERE SCHEDULED TODAY FOR THE FOLLOWING PROCEDURES: LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS), BULLECTOMY AND TALC PLEURODESIS. PARTICIPANT DID NOT REPORT ANY ADDITIONAL INFORMATION AT THIS TIME AND WAS UNABLE TO TALK TO STUDY RN. PI HAS ASSESSED THIS EVENT AS NOT RELATED TO STUDY PRODUCT.' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:07:44
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Feb 2021 22:05:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:05:28

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EAB) (1725)

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**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 22:05:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 22:05:28

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 22:05:28

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	23 Apr 2021 19:34:28
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 14:41:51
User entered	(b) (4), (b) (6)	24 Mar 2021 14:41:48
'USA-US110-2020-mRNA-1273-P301000003'		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:19:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:19:54
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:40:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:01:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:01:24
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'per query, additional information has been added. Per query, AE is grade 3' (Site from DM).	Mario Portilla (b) (4)	06 Apr 2021 16:51:35
Data point term sent to Coder	System	06 Apr 2021 16:51:16
Coding entries removed.	Mario Portilla (b) (4)	06 Apr 2021 16:50:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 16:50:42
User entered 'ACUTE HYPOXEMIA RESPIRATORY FAILURE (worsening)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 16:50:42
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX). If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:22:07
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:09:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 22:09:49
Data point term sent to Coder	System	10 Mar 2021 22:18:53
User entered 'Acute hypoxemia respiratory failure'	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '19 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Mario Portilla (b) (4)	10 Mar 2021 22:21:55
	(b) (4)	
User entered '29 Dec 2020'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	10 Mar 2021 22:21:55
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 22:21:55
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 22:21:55
User entered '23 Dec 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	10 Mar 2021 22:21:55
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	10 Mar 2021 22:18:35
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Mar 2021 22:18:35
User entered empty.	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 22:18:35



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	10 Mar 2021 22:21:55
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Mar 2021 22:18:35
User entered 'Yes (Y)'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Mar 2021 22:21:55
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	10 Mar 2021 22:21:55
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		10 Mar 2021 22:21:55
User entered '1' reason for change: Data Entry Error	Mario Portilla (b) (4)	10 Mar 2021 22:21:55
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Mar 2021 22:18:35
User entered '0'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '19 Dec 2020'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Not Related (NOT RELATED)'	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:44:36
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' answered with 'per query, information updated' (Site from Safety). Signature has been broken.	Mario Portilla (b) (4) (b) (4)	01 Apr 2021 17:54:05
	Mario Portilla (b) (4) (b) (4)	01 Apr 2021 17:51:30
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Mario Portilla (b) (4) (b) (4)	01 Apr 2021 17:51:30
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly for the events, worsening left pneumothorax and acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:57:07
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Not Applicable (NOT APPLICABLE)'	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'PV Query: Please consider updating action take for the even acute hypoxemia respiratory failure from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:44:45
Query 'PV Query: Please consider updating action take for the even acute hypoxemia respiratory failure from none to not applicable.' answered with 'per query, information has been updated' (Site from Safety).	Mario Portilla (b) (4)	01 Apr 2021 17:50:20
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	01 Apr 2021 17:49:36
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Mario Portilla (b) (4)	01 Apr 2021 17:49:36
	(b) (4)	
User opened query 'PV Query: Please consider updating action take for the even acute hypoxemia respiratory failure from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:56:27
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered 'None (NONE)'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

None

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	31 Mar 2021 20:24:42
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	31 Mar 2021 20:21:05
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 20:21:05
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mario Portilla (b) (4)	31 Mar 2021 20:21:05
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:33:30
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:21:52
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:21:05
User entered '0' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:21:05
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 05:28:59
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered '1'	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
Signature has been broken.	Mario Portilla (b) (4)	31 Mar 2021 20:24:42
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Mario Portilla (b) (4)	31 Mar 2021 20:24:42
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Malithi Desilva (b) (4)	23 Mar 2021 14:32:05
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	10 Mar 2021 22:18:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:18:35
	Mario Portilla (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'PV Query: Please clarify event terms of acute hypoxemia respiratory failure and acute hypoxemic respiratory failure (secondary to recurrent left pneumothorax). Please consider whether these events are duplicated or if the event acute hypoxemia respiratory failure should be updated to worsening of acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:45:03
Query 'PV Query: Please clarify event terms of acute hypoxemia respiratory failure and acute hypoxemic respiratory failure (secondary to recurrent left pneumothorax). Please consider whether these events are duplicated or if the event acute hypoxemia respiratory failure should be updated to worsening of acute hypoxemia respiratory failure.' answered with 'These medical diagnosis were listed separately in the participant's discharge summary. Do not understand how this can be listed as duplicate, please clarify' (Site from Safety).	Mario Portilla (b) (4) (b) (4)	01 Apr 2021 17:57:03
User opened query 'PV Query: Please clarify event terms of acute hypoxemia respiratory failure and acute hypoxemic respiratory failure (secondary to recurrent left pneumothorax). Please consider whether these events are duplicated or if the event acute hypoxemia respiratory failure should be updated to worsening of acute hypoxemia respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:56:03
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Mar 2021 22:23:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 22:23:55
User entered 'USA-US110-2020-MRNA-1273-P301000003' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:23:55

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:02:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Mar 2021 22:18:35
User entered empty.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:18:35

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 22:18:35

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 22:18:35



**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 22:18:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:48:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:48:37
Data point term sent to Coder	System	31 Mar 2021 20:17:54
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:17:17
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:17:17
User entered 'TREMORS (HANDS) WORSENER' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:17:17
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:51:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 12:51:36
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
Data point term sent to Coder	System	17 Mar 2021 15:30:32
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:29:47
User entered 'TReMORS (HANDS) WORESENER' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	17 Mar 2021 15:29:47

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:33:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 11:33:55
Data point term sent to Coder	System	11 Mar 2021 19:57:29
User entered 'Trmors (hands) worsened'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:56:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	11 Mar 2021 20:11:03
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	11 Mar 2021 20:11:03
User entered '23 Dec 2020' reason for change: Per Query Resolution	Mario Portilla (b) (4)	11 Mar 2021 20:11:03
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	11 Mar 2021 19:56:45
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	11 Mar 2021 19:56:45
User entered '01 Jul 2020'	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User entered empty.	System	11 Mar 2021 19:56:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:13:16
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'Per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:17:58
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 05:29:11
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:56:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User entered '13 Jan 2021' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered empty.	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:56:45

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User entered empty.	System	11 Mar 2021 19:56:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR-RQ: Response noted. However, please review severity as a worsening condition should be higher than Grade1/Mild. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:17:01
Query 'Per DM CLR-RQ: Response noted. However, please review severity as a worsening condition should be higher than Grade1/Mild. Update as appropriate. Otherwise, provide clarification.' answered with 'per query, information was updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 16:58:57
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 16:58:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 16:58:25
User opened query 'Per DM CLR-RQ: Response noted. However, please review severity as a worsening condition should be higher than Grade1/Mild. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 15:02:47
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 15:02:47
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' answered with 'per query, information was updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:18:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan (b) (4)	27 Mar 2021 05:29:17 23 Mar 2021 15:54:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:56:45



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'None (NONE)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'l'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:14:49
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:56:45

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	11 Mar 2021 19:56:45
	Mario Portilla (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:56:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User entered '0'	System	11 Mar 2021 19:56:45

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08
User entered '1'	System	11 Mar 2021 19:56:45

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:08

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. also please provide the end date.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:06:53
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. also please provide the end date.' answered with 'Participant followed-up with scheduled primary physician visit and was prescribed Budesonide. Documented 12/09/2020 call with participant reveals that participant denies COVID symptoms and/or COVID contacts.' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:46:30
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. also please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:08:11
Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	29 Mar 2021 05:07:37
Per MM, please provide the end date.Thank you. ' canceled (Site from DM).		
User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	29 Mar 2021 05:07:20
Per MM, please provide the end date.Thank you. ' (Site from DM).		
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 14:32:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Mar 2021 14:32:38
Data point term sent to Coder	System	11 Mar 2021 19:58:30

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COPD worsened'	(b) (4), (b) (6)	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '01 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User entered empty.	System	11 Mar 2021 19:58:05



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:34:09
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:50:00
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 05:29:33
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Mar 2021 20:48:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	31 Mar 2021 20:48:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	31 Mar 2021 20:34:03
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User entered '13 Jan 2021' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered empty.	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:58:05

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User entered empty.	System	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:53:40
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' answered with 'per query resolution information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:47:50
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 05:29:28
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	



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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'None (NONE)'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	11 Mar 2021 19:58:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Mar 2021 19:58:05
User entered '0'	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:21
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:48:22
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Mario Portilla (b) (4) (b) (4)	31 Mar 2021 20:34:03
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	



**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:34:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	11 Mar 2021 19:58:05
	(b) (4)	

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User entered '0'	System	11 Mar 2021 19:58:05

US3842027

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14
User entered '1'	System	11 Mar 2021 19:58:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:14

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Procedural site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:59:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:59:45
Data point term sent to Coder	System	06 Apr 2021 19:51:59
User entered 'Severe Pain at left rib cage, insertion site where chest tube was removed (after left pneumothorax -resolved)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '23 Dec 2020'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User entered empty.	System	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '13 Jan 2021'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User entered empty.	System	06 Apr 2021 19:51:03



US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03



**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Not Applicable (NOT APPLICABLE)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'None (NONE)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03



US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'l'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered '0'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

**US3842027**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered empty.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 19:34:28
User entered 'tramadol-acetaminophen 37.5/325 mg PRN was prescribed at discharge for pain management at left rib cage after chest tube was removed'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User entered '0'	System	06 Apr 2021 19:51:03

US3842027

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22
User entered 'I'	System	06 Apr 2021 19:51:03

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:22



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:02:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:15
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:40:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User closed query 'Per MM, please enter missing data.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 13:14:22
Query 'Per MM, please enter missing data.' answered with 'entering' (Site from DM).	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:23:27
User opened query 'Per MM, please enter missing data.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:16:13
User entered 'Yes (Y)'	Malithi Desilva (b) (4) (b) (4)	18 Sep 2020 17:29:20

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 21:52:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:52:57
Data point term sent to Coder	System	19 Feb 2021 21:52:50
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 21:52:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:13:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:13:10
Data point term sent to Coder	System	21 Jan 2021 22:12:23
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 22:11:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 21:28:08

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Mario Portilla (b) (4) (b) (4)	21 Jan 2021 21:28:08  21 Jan 2021 21:27:39 21 Jan 2021 21:27:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:09:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:09:28
Data point term sent to Coder User entered 'Humalog'	System Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:42 08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:42:23
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'TYPE II DIABETES' reason for change: Per Query Resolution	(b) (4) Mario Portilla (b) (4) (b) (4)	19 Feb 2021 21:52:37
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 22:11:27
User entered 'TYPE I DIABETES' reason for change: Per Query Resolution	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 22:11:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Type II Diabetes'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '36'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'IU (IU)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'twice daily (BID)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:25:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4) (b) (4)	21 Jan 2021 21:27:02
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 21:27:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1980'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:26:08
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:26:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
User entered '23 Dec 2020' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:17:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:25:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 14:25:33
User entered 'No (N)' reason for change: Data Entry Error	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:33
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 14:25:21
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:25:21

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User entered '2'	System	08 Oct 2020 14:25:21

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User entered '1'	System	08 Oct 2020 14:25:21

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:39
User entered '804 (804)'	System	08 Oct 2020 14:25:21

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 17:18:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 17:18:54
Data point term sent to Coder Coding entries removed.	System	10 Mar 2021 17:17:47
	Malithi Desilva (b) (4)	10 Mar 2021 17:17:01
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 22:12:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 22:12:07
Data point term sent to Coder Coding entries removed.	System	21 Jan 2021 22:11:21
	Mario Portilla (b) (4)	21 Jan 2021 22:11:01
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 21:30:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Mario Portilla (b) (4) (b) (4)	21 Jan 2021 21:30:08  21 Jan 2021 21:29:39 21 Jan 2021 21:29:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:17:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Levemir'	Coder Import (b) (4) (b) (4) System Christie Lyn Costanza (b) (4)	08 Oct 2020 21:17:53  08 Oct 2020 14:28:46 08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:22:27
User closed query 'please review indication as source states type II. please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 15:21:41
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Query 'please review indication as source states type II. please review and update accordingly' answered with 'Confirmed with MH and updated' (Site from CRA).	(b) (4)	
Signature has been broken.	Malithi Desilva (b) (4)	10 Mar 2021 17:17:18
	(b) (4)	
User entered 'TYPE II DIABETES' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	10 Mar 2021 17:17:01
	(b) (4)	
User opened query 'please review indication as source states type II. please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 16:43:13
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
DataPoint Un-verified.	Mario Portilla (b) (4)	21 Jan 2021 22:11:01
	(b) (4)	
User entered 'TYPE I DIABETES' reason for change: Per Query Resolution	Mario Portilla (b) (4)	21 Jan 2021 22:11:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Type II Diabetes'	Christie Lyn Costanza	08 Oct 2020 14:28:18
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '56'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'IU (IU)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:44:27
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4)	21 Jan 2021 21:29:19
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	21 Jan 2021 21:29:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1980'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:22:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 19:17:47
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	16 Mar 2021 19:17:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Mar 2021 19:17:47
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza	08 Oct 2020 14:28:18
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 15:22:30
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
DataPoint Un-verified.	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 19:17:47
Signature has been broken.	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 19:17:47
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 19:17:47
User signature succeeded.	(b) (4) Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	(b) (4) Christie Lyn Costanza	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:28:18

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User entered '1'	System	08 Oct 2020 14:28:18

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User entered '1'	System	08 Oct 2020 14:28:18

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:49:48
User entered '804 (804)'	System	08 Oct 2020 14:28:18

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: TORASEMIDE, PRODUCTSYNONYM: TORSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:21:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:21:24
Data point term sent to Coder	System	08 Oct 2020 14:29:47
User entered 'Torsemide'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 06:46:35
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated MH eCRF' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:46:08
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:58:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Elevated Blood Pressure'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '20'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza	08 Oct 2020 14:29:03
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1990'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:29:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:29:03



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:29:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 15:59:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 15:59:10
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 15:57:08
Coding entries removed.	Malithi Desilva (b) (4)	21 Oct 2020 15:56:10
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 21:21:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 21:21:23
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 14:29:48
User entered 'Tamsulosin'	Christie Lyn Costanza	08 Oct 2020 14:29:47
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 08:08:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
Query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' answered with 'added medical condition/diagnosis per query ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	21 Oct 2020 15:56:48
User entered 'PROSTATE cancer' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	21 Oct 2020 15:56:10
User opened query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:18:28
User entered 'Prostate'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0.4'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza	08 Oct 2020 14:29:47
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and correct. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:45:11
Query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and correct. Thankyou.' answered with 'verified and corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:46:03
User opened query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and correct. Thankyou.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:09:59
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 2008'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza	08 Oct 2020 14:29:47
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:29:47



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:29:47

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:29:47

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:39:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:39:21
Data point term sent to Coder	System	21 Oct 2020 15:57:09
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	21 Oct 2020 15:57:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:57:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:57:54
Data point term sent to Coder	System	08 Oct 2020 14:31:50
User entered 'Finestrade'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 08:10:29
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
Query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' answered with 'added medical condition/diagnosis per query ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	21 Oct 2020 15:57:08
User entered 'PROSTATE cancer' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	21 Oct 2020 15:57:03
User opened query 'Per CDM: Indication is recorded as "Prostate". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs (Like, Prostate cancer).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:18:49
User entered 'Prostate'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '5'	Christie Lyn Costanza	08 Oct 2020 14:30:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and update correctly. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:45:48
Query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and update correctly. Thankyou.' answered with 'verified and corrected' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:46:26
User opened query 'Per CDM: The start date of the Con Med is prior to the start date of the Medical history. Please verify and update correctly. Thankyou.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:11:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 2008'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza	08 Oct 2020 14:30:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:30:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:30:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 21:26:39
Data point term sent to Coder	System	08 Oct 2020 14:31:50
User entered 'Multivitamin'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:46:17
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:46:10
Query 'Per DM CLR: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:38:28
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:38:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:38:22
User opened query 'Per DM CLR: Prophylaxis = NO. However, vitamins. Supplements, contraceptives and vaccines are considered for prophylactic use. Please update response to Prophylaxis field as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:00:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Nutritional Supplement'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'I'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'tablet (TABLET)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1980'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:31:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:31:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:40:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:40:48
Data point term sent to Coder	System	08 Oct 2020 14:32:51
User entered 'Topiramate'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 06:46:03
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated in MH eCRF per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:40:58
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:00:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Tremors'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '100'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'twice daily (BID)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 2010'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 14:32:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:32:19



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:32:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:26:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:26:41
Data point term sent to Coder	System	08 Oct 2020 14:34:53
User entered 'Metoprolol Taetrate'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 06:44:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated in MH eCRF' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	11 Dec 2020 21:55:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:01:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Atrial Fibrillation'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '50'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'I'	Christie Lyn Costanza	08 Oct 2020 14:34:38
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 14:34:38



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 14:34:38

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 14:34:38

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:17:49
Data point term sent to Coder	System	08 Oct 2020 15:24:02
User entered 'Aspirin'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Heart Health'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '81'	Christie Lyn Costanza	08 Oct 2020 15:23:08
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mg (mg)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1990'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 15:25:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 15:25:24
User entered 'No (N)' reason for change: Data Entry Error	Christie Lyn Costanza	08 Oct 2020 15:25:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 15:23:08
User entered empty.	Christie Lyn Costanza	08 Oct 2020 15:23:08
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:23:08

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 15:23:08

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:18:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:18:20
Data point term sent to Coder	System	08 Oct 2020 15:25:03
User entered 'Potassium'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:48:11
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:47:22
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:37:56
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:37:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:37:50
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:01:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Nutritional Supplement'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '20'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Other (OTHER)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'meq'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once daily (QD)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Oral (ORAL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

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

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'un UNK 1995'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Yes (Y)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 15:24:15

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 15:24:15

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:18:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:18:27
Data point term sent to Coder	System	08 Oct 2020 15:26:06
User entered 'Flu Vaccine'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:50:09
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:47:32
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:43:29
DataPoint Un-verified.	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:43:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:43:23
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:01:50
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Vaccine'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0.5'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'mL (mL)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'once (ONCE)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered empty.	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '20 Aug 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '0'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered '20 Aug 2020'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 15:22:36
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	08 Oct 2020 15:25:09

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User entered empty.	System	08 Oct 2020 15:25:09

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User entered empty.	System	08 Oct 2020 15:25:09



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:05
User entered empty.	System	08 Oct 2020 15:25:09

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:44:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:44:57
Data point term sent to Coder	System	10 Mar 2021 22:10:45
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:09:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:01
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: After updating the medication name field, please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening COLLAPSED LUNG. Alternatively, consider updating the AE # 01 to reflect this, and make sure "Other Action Taken" on the AE eCRF indicates that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:03:05
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components, the dose/units, and specify the # of puffs for dose/units per eCRF completion guidelines for combination medications.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:03:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:22:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:22:02
Data point term sent to Coder	System	19 Feb 2021 22:19:41
Query 'Per DM CLR: After updating the medication name field, please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening COLLAPSED LUNG. Alternatively, consider updating the AE # 01 to reflect this, and make sure "Other Action Taken" on the AE eCRF indicates that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'information updated per query' (Site from DM).	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:19:23
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components, the dose/units, and specify the # of puffs for dose/units per eCRF completion guidelines for combination medications.' answered with 'updated per query' (Site from DM).	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:18:34
Data point term sent to Coder	System	19 Feb 2021 22:14:36
Coding entries removed.	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:14:22
User entered 'BUDESONIDE AND FORMOTEROL FUMARATE DIHYDRATE INHALATION AEROSOL' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:14:22

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: After updating the medication name field, please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening COLLAPSED LUNG. Alternatively, consider updating the AE # 01 to reflect this, and make sure "Other Action Taken" on the AE eCRF indicates that a CM was given. Please review and reconcile CM and the AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 13:29:00
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported. Please update the medication name field to include both components, the dose/units, and specify the # of puffs for dose/units per eCRF completion guidelines for combination medications.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 13:27:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDs, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:56:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:56:07
Data point term sent to Coder	System	09 Dec 2020 14:44:39
User entered 'Budesonide inhaler'	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:04
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:27:26
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Per CDM Re-Query: Site response noted; however, please note there is NO AE reflecting "COPD Worsening". Please review and update the AE page accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 07:53:06
Query 'Per CDM Re-Query: Site response noted; however, please note there is NO AE reflecting "COPD Worsening". Please review and update the AE page accordingly. Thank you.' answered with 'per query, additional information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	11 Mar 2021 20:07:43
User opened query 'Per CDM Re-Query: Site response noted; however, please note there is NO AE reflecting "COPD Worsening". Please review and update the AE page accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:16:25
User closed query 'Per DM CLR RQ: Please verify if this medication was added because the patient's medical history of COPD worsened or used for ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX . Please review and reconcile all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:16:25
Query 'Per DM CLR RQ: Please verify if this medication was added because the patient's medical history of COPD worsened or used for ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX . Please review and reconcile all applicable eCRFs if appropriate. ' answered with 'Per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:29:18
DataPoint Un-verified.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:09:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:09:59
User entered 'COPD worsened' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:09:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:17
User opened query 'Per DM CLR RQ: Please verify if this medication was added because the patient's medical history of COPD worsened or used for ACUTE HYPOXEMIC RESPIRATORY FAILURE (SECONDARY TO RECURRENT LEFT PNEUMOTHORAX . Please review and reconcile all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:38:52
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User closed query 'Per DM CLR: Please note that there is no AE matching the COPD Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:03:07
Query 'Per DM CLR: Please note that there is no AE matching the COPD Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'per query, information updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:19:52
User entered 'COPD' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:19:36
User opened query 'Per DM CLR: Please note that there is no AE matching the COPD Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 13:29:42
User entered 'collapsed lung, COPD'	Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:27
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '80/4.5'	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:30
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'ug (ug)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:33
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:36
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'twice daily (BID)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:45
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:48
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:55
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'UN Dec 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:51:57
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '0'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:52:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:52:06
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	09 Dec 2020 14:44:36
	Malithi Desilva (b) (4)	
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:52:17
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	09 Dec 2020 14:44:36

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Dec 2020 14:44:36

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Dec 2020 14:44:36

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Dec 2020 14:44:36

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 07:18:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:18:42
Data point term sent to Coder	System	10 Mar 2021 22:51:47
User entered 'topiramate'	Mario Portilla (b) (4) (b) (4)	10 Mar 2021 22:50:45

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Mar 2021 22:50:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 22:50:57
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	10 Mar 2021 22:50:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 22:50:45
User entered empty.	Mario Portilla (b) (4)	10 Mar 2021 22:50:45
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'hand tremors worsening'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '150'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered 'mg (mg)'	Mario Portilla (b) (4)	10 Mar 2021 22:50:45
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'twice daily (BID)'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Oral (ORAL)'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	11 Mar 2021 20:13:24
User entered '23 Dec 2020' reason for change: Data Entry Error	System	11 Mar 2021 20:13:24
User entered '23 Dec 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	11 Mar 2021 20:13:24
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	11 Mar 2021 20:13:24
User entered '23 Dec 2021' reason for change: Data Entry Error	System	11 Mar 2021 20:13:14
User entered '23 Dec 2021' reason for change: Data Entry Error	Mario Portilla (b) (4)	11 Mar 2021 20:13:14
User entered '01 Jul 2020'	(b) (4)	11 Mar 2021 20:13:14
	Mario Portilla (b) (4)	10 Mar 2021 22:50:45
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	10 Mar 2021 22:50:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	10 Mar 2021 22:50:45
	(b) (4)	

**US3842027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Mar 2021 22:50:45

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 22:50:45

**US3842027**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 22:50:45



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 19:25:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 19:25:54
Data point term sent to Coder	System	16 Mar 2021 19:24:51
User entered 'Humalog'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:24:10

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Diabetes II'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '20'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'IU (IU)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'other (OTHER)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'before meals'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:24:10
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:24:10



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:24:10

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 19:24:10

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 19:27:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 19:27:02
Data point term sent to Coder	System	16 Mar 2021 19:25:52
User entered 'Levemir'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:25:40

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Diabetes II'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '50'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'IU (IU)'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:11:55
Signature has been broken.	(b) (4)	25 Mar 2021 21:27:18
	Mario Portilla (b) (4)	25 Mar 2021 21:27:18
	(b) (4)	
User entered 'once daily (QD)' reason for change: Per Query Resolution	Mario Portilla (b) (4)	25 Mar 2021 21:27:18
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
	(b) (4)	
User entered 'other (OTHER)'	Mario Portilla (b) (4)	16 Mar 2021 19:25:40
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User closed query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:29:12
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:11:55
Query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'per query, information has been updated' (Site from DM).	(b) (4) Mario Portilla (b) (4)	25 Mar 2021 21:28:04
Signature has been broken.	(b) (4) Mario Portilla (b) (4)	25 Mar 2021 21:27:18
User entered empty; reason for change Data Entry Error	(b) (4) Mario Portilla (b) (4)	25 Mar 2021 21:27:18
User opened query 'Per CDM: Per page 54 of CCGs v5.0, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:54:19
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'bed time'	(b) (4) Mario Portilla (b) (4)	16 Mar 2021 19:25:40

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2305 of 2740

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:25:40
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:25:40
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 21:27:18
User entered empty.	System	16 Mar 2021 19:25:40

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 21:27:18
User entered empty.	System	16 Mar 2021 19:25:40

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 21:27:18
User entered empty.	System	16 Mar 2021 19:25:40

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:19:40
Data point term sent to Coder	System	16 Mar 2021 19:27:53
User entered 'enoxaparin'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:33:52
User closed query 'Per DM CLR: The indication signifies prophylaxis (DVT Prevention). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:11:18
Query 'Per DM CLR: The indication signifies prophylaxis (DVT Prevention). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'Per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:21:40
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:20:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:20:19
User opened query 'Per DM CLR: The indication signifies prophylaxis (DVT Prevention). However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:20:18
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'DVT prevention'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '40'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'mg (mg)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'once daily (QD)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '19 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:26:58
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
User entered '1'	System	16 Mar 2021 19:26:58

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
User entered '1'	System	16 Mar 2021 19:26:58

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:15
User entered '804 (804)'	System	16 Mar 2021 19:26:58

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: PARACETAMOL;TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: TRAMADOL/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 11:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:55:43
Data point term sent to Coder	System	16 Mar 2021 19:31:03
User entered 'tramadol-acetaminophen'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:30:55

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:08:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' answered with 'Per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 19:54:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:21:09
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'pain, left rib cage s/p surgery, discharge to home'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:30:55

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '37.5 / 325'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:30:55

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'mg (mg)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'other (OTHER)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:30:55

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'every 4 hours PRN'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Oral (ORAL)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:30:55

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '13 Jan 2021'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:30:55
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
User entered empty.	System	16 Mar 2021 19:30:55

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
User entered empty.	System	16 Mar 2021 19:30:55

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:50:22
User entered empty.	System	16 Mar 2021 19:30:55



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 19:32:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 19:32:54
Data point term sent to Coder	System	16 Mar 2021 19:32:05
User entered 'docusate sodium'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:32:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition or AE 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 or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:10:04
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE 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 or AE eCRF. ' answered with 'per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:33:31
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE 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 or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:22:15
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'constipation'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:32:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '100'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'mg (mg)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'twice daily (BID)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Oral (ORAL)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '23 Dec 2020'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Yes (Y)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	16 Mar 2021 19:32:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 19:32:03



US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:32:03

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 19:32:03

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 12:21:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:21:42
Data point term sent to Coder	System	16 Mar 2021 19:53:38
User entered 'Oxygen, supplemental (via rebreather mask)'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 May 2021 09:50:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Participant was admitted to Emergency Dept. on 9/19/2020 for collapsed left lung. Participants oxygen saturation was 92% and was placed on supplemental oxygen via rebreather mask on 9/19/2020 at arrival to ED and was discontinued on 9/19/2020 after admitting assessment was completed by ED physician' (Site from DM).	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:27:44
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:22:33
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:54:36
User entered 'Oxygen saturation 92%'	Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '2'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Other (OTHER)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'liter / min.'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'other (OTHER)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'continuous'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '19 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '0'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4) Mario Portilla (b) (4) (b) (4)	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '19 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'No (N)'	(b) (4)	
	Mario Portilla (b) (4)	16 Mar 2021 19:53:19
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
User entered empty.	System	16 Mar 2021 19:53:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
User entered empty.	System	16 Mar 2021 19:53:19

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:25
User entered empty.	System	16 Mar 2021 19:53:19

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:33:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 22:12:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 22:12:31
Data point term sent to Coder	System	06 Apr 2021 17:20:08
User entered 'Albuterol sulfate (0.083 %)'	Mario Portilla (b) (4) (b) (4)	06 Apr 2021 17:19:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'No (N)'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'asthma'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered '2.5'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'mg (mg)'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:02:02**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'other (OTHER)'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'every 6 hours'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'I'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'Yes (Y)'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'No (N)'	Mario Portilla (b) (4)	06 Apr 2021 17:19:59
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:19:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:19:59

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:19:59

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 17:24:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 17:24:14
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 17:23:15
User entered 'Ipratropium bromide'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'No (N)'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'Asthma'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered '0.5'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'mg (mg)'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'four times daily (QID)'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	



US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'I'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'Yes (Y)'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered empty.	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:52
User entered 'No (N)'	Mario Portilla (b) (4)	06 Apr 2021 17:22:31
	(b) (4)	

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:22:31

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 17:22:31

US3842027

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:02:02**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 17:22:31



US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:02:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:15
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:22:29
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 18:02:43
	Christie Lyn Costanza	
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '21 Dec 2020'	(b) (4)	19 Feb 2021 22:23:22
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User closed query ' Per CDM: For LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 08:54:14
Query ' Per CDM: For LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' answered with 'This surgical procedure occurred after enrollment. Per protocol, this is not an event to be documented as a "medical history condition".' (Site from DM).	Mario Portilla (b) (4) (b) (4)	12 Mar 2021 14:20:45
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	12 Mar 2021 14:15:49
User entered 'LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	12 Mar 2021 14:15:49
User opened query ' Per CDM: For LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:57:45
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered 'LEFT VIDEO ASSISTED THORACOSCOPIC SURGERY (LVATS)'	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:23:22

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Signature has been broken.	(b) (4)	23 Mar 2021 13:51:21
User entered 'Adverse Event (AE)' reason for change: New Information	Malithi Desilva (b) (4)	23 Mar 2021 13:51:21
User signature succeeded.	(b) (4)	26 Feb 2021 19:02:23
User entered 'Medical History (MH)'	Shobha Swaminathan	19 Feb 2021 22:23:22
	(b) (4)	
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:02

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	19 Feb 2021 22:23:22
	Mario Portilla (b) (4)	
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '21 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	19 Feb 2021 22:24:20
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User closed query 'Per CDM: For BULLECTOMY - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:54:19
Query 'Per CDM: For BULLECTOMY - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' answered with 'This surgical procedure occurred after enrollment. Per protocol, this is not an event to be documented as a "medical history condition".' (Site from DM).	Mario Portilla (b) (4) (b) (4)	12 Mar 2021 14:21:06
User opened query 'Per CDM: For BULLECTOMY - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:58:31
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered 'BULLECTOMY'	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:24:20

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Signature has been broken.	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 13:51:30
User entered 'Adverse Event (AE)' reason for change: New Information	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 13:51:30
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
User entered 'Medical History (MH)'	Mario Portilla (b) (4)	19 Feb 2021 22:24:20
	(b) (4)	



US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:43:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	19 Feb 2021 22:24:20
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:02

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '21 Dec 2020'	(b) (4)	
	Mario Portilla (b) (4)	19 Feb 2021 22:25:05
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:02

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User closed query 'Per CDM: For TALC PLEURODESIS - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:54:22
Query 'Per CDM: For TALC PLEURODESIS - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' answered with 'This surgical procedure occurred after enrollment. Per protocol, this is not an event to be documented as a "medical history condition".' (Site from DM).	Mario Portilla (b) (4) (b) (4)	12 Mar 2021 14:21:21
User opened query 'Per CDM: For TALC PLEURODESIS - indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:02:28
User signature succeeded.	Shobha Swaminathan (b) (4)	26 Feb 2021 19:02:23
User entered 'TALC PLEURODESIS'	Mario Portilla (b) (4) (b) (4)	19 Feb 2021 22:25:05

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Signature has been broken.	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 13:51:42
User entered 'Adverse Event (AE)' reason for change: New Information	(b) (4)	
	Malithi Desilva (b) (4)	23 Mar 2021 13:51:42
User signature succeeded.	(b) (4)	
	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
User entered 'Medical History (MH)'	Mario Portilla (b) (4)	19 Feb 2021 22:25:05
	(b) (4)	

US3842027

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:02

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:24:31
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered empty.	(b) (4)	
	Mario Portilla (b) (4)	19 Feb 2021 22:25:05
	(b) (4)	

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '22/Dec/2020 16:39'	(b) (4) System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:02:02

**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)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '22/Jan/2021 15:54'	(b) (4) System	22 Jan 2021 15:54:29



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:02:02

**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)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:15:19
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 15:54:29

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '27/Jan/2021 13:15'	(b) (4) System	27 Jan 2021 18:15:14

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:02:02

**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)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:15:19
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 18:15:14

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
User entered '08/Feb/2021 09:08'	(b) (4) System	08 Feb 2021 14:08:44

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:02:02

**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)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 14:08:44

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered '22/Feb/2021 11:45'	(b) (4) System	22 Feb 2021 16:46:01

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:02:02

**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)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:46:01

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '11/Mar/2021 07:12'	(b) (4) System	11 Mar 2021 15:12:12



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:17
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 15:12:12

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza	05 Feb 2021 23:20:22
	(b) (4)	

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '16/Mar/2021 11:41'	(b) (4) System	16 Mar 2021 15:41:32

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:31:36
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 15:41:32

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '17/Mar/2021 10:31'	(b) (4) System	17 Mar 2021 14:32:05

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 16:20:00
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 14:32:05

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '17/Mar/2021 12:20'	(b) (4) System	17 Mar 2021 16:20:34

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:02:05
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 16:20:34

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '22/Mar/2021 12:02'	(b) (4) System	22 Mar 2021 16:02:38



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:26:20
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 16:02:38

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (11)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '22/Mar/2021 12:27'	(b) (4) System	22 Mar 2021 16:27:44

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:42:37
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 16:27:44

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (12)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered '22/Mar/2021 12:42'	(b) (4) System	22 Mar 2021 16:43:04

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:54:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:43:04

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (13)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:11:55
User entered '24/Mar/2021 10:48'	(b) (4) System	24 Mar 2021 14:48:14

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 10:02:02

**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)	19 Apr 2021 18:37:28
User signature succeeded.	Shobha Swaminathan	30 Mar 2021 17:11:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:48:14

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (14)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered '01/Apr/2021 05:51'	System	01 Apr 2021 12:52:02



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 10:02:02

**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.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 12:52:02

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25



US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (15)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered '02/Apr/2021 09:45'	System	02 Apr 2021 13:45:40

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (15)

Generated On: 10 Jun 2021 10:02:02

**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.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 13:45:40

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'USA-US110-2020-MRNA-1273-P301000003'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
Un-reviewed for Safety.	(b) (4)	22 Feb 2021 16:38:25
Signature has been broken.	System	22 Feb 2021 16:38:25
User entered 'Yes (Y)'	System	22 Feb 2021 16:38:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Yes (Y)'	System	22 Dec 2020 21:38:48



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'No (N)'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Shobha'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Swaminathan'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '185, south orange ave'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered 'Newark'	System	22 Dec 2020 21:38:48

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 14:08:50
User entered empty.	System	08 Feb 2021 14:08:44
User entered 'New Jersey'	Christie Lyn Costanza (b) (4)	05 Feb 2021 23:20:22



**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:39:10
User entered '07103'	System	22 Dec 2020 21:38:48

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:02**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 16:31:39
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:15
User entered 'US'	System	22 Dec 2020 21:39:25

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '16'	System	07 Apr 2021 13:20:06
User entered '15'	System	02 Apr 2021 13:45:40
User entered '14'	System	01 Apr 2021 12:52:02
User entered '13'	System	24 Mar 2021 14:48:14
User entered '12'	System	22 Mar 2021 16:43:04
User entered '11'	System	22 Mar 2021 16:27:44
User entered '10'	System	22 Mar 2021 16:02:38
User entered '9'	System	17 Mar 2021 16:20:34
User entered '8'	System	17 Mar 2021 14:32:05
User entered '7'	System	16 Mar 2021 15:41:32
User entered '6'	System	11 Mar 2021 15:12:12
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:02:23
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 16:46:01
User entered '5'	System	22 Feb 2021 16:46:01
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:42:03
	(b) (4)	
User entered '4'	System	08 Feb 2021 14:08:44
User entered '3'	System	27 Jan 2021 18:15:14
User entered '2'	System	22 Jan 2021 15:54:29
User entered '1'	System	22 Dec 2020 21:39:25

**US3842027**

**Folder: SAE USA-US110-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (16)**

**Generated On: 10 Jun 2021 10:02:02**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered '07/Apr/2021 06:20'	System	07 Apr 2021 13:20:06

US3842027

Folder: SAE USA-US110-2020-MRNA-1273-P301000003

Form: Safety Report Form (16)

Generated On: 10 Jun 2021 10:02:02

**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.	Shobha Swaminathan	28 Apr 2021 10:32:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:37:28
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 13:20:06